

SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	HyperCard® (10mg Coated Tablets for Cats)
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 therapeutic treatment of feline primary hypertrophic cardiomyopathy.
Uses advised against:	<p>Not for human use.</p> <ul style="list-style-type: none"> • Do not use in animals suffering from AV block (2nd or 3rd), hypotension or sick sinus syndrome. • Diltiazem should not be given to animals suffering from hepatic disease. • Do not use in animals suffering from renal disease. • Do not use in cats less than 12 months old. • Do not use in cats weighing less than 3 kg. • Do not use in animals that are hypersensitive to Diltiazem. • Do not use in cats with severe bradycardia or arterial hypotension. • Do not use in conjunction with β blockers, digitalis or digoxin. • Do not use in pregnant or lactating females.
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	% weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 33286-22-5 2. 251-443-3 3. Not Available 4. Not Available	0.1	Diltiazem hydrochloride	Acute Toxicity (Oral) Category 4, Carcinogenicity Category 2, Reproductive Toxicity Category 2, Lactation Effects, Chronic Aquatic Hazard Category 3; H302, H351, H361, H362, H412 ¹
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:	Wash immediately with copious quantities of water and seek medical attention, showing the label or package leaflet to the physician.
Skin contact:	Wash immediately with copious quantities of water. Observe for adverse reactions and seek medical attention if necessary, showing the label or package leaflet to the physician.
Inhalation:	Inhalation is unlikely due to the nature and packaging of the product. Remove to fresh air and give oxygen if needed. Seek medical attention.
Ingestion:	Remove material from mouth. Seek medical attention: gastric lavage or orally activated charcoal, followed by administration of inotropes and induction of cardiac pacing where necessary. IV Ca ²⁺ carbonate may aid in restoring normal cardiac function.

4.2 Most important symptoms and effects, both acute and delayed

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:	Water spray, dry chemical, carbon dioxide, foam.
Unsuitable:	None.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	Unknown.
5.3 Special protective actions for fire-fighters:	
Firefighting:	Evacuate area. Wear self-contained breathing apparatus and protective clothing.
Fire / explosion hazard:	Material assumed to be combustible. Hazardous combustion products include toxic fumes, sulphur oxides, nitrogen oxides, hydrogen chloride.

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:	Wear adequate eye protection and gloves. Wash residues and small spillages to waste with copious quantities of water.
Major Spills:	Observe local legislation. Add an inert absorbent to larger releases, and shovel/sweep into an appropriate container for waste disposal. Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment.



SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe Handling:	Wash hands after use as tartrazine, in the colour coating may cause allergic reaction in people who are susceptible. Do not break tablets. 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.
-----------------------	---

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. Keep the blister strips in the outer carton. Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
----------------------------	---

Storage incompatibility:	Unknown.
---------------------------------	----------

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:

Not Available

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: HyperCard®: A yellow coated biconvex tablet.
 Diltiazem hydrochloride: White crystalline powder.

Container: Tablets are located in a preformed low density polyethylene base containing 10 tablets and sealed with PC 100 laminate comprising of aluminium foil and a heat seal lacquer. Once sealed, 3 blisters of 10 tablets (30 tablets) are placed in a cardboard box.

Physical state: Solid

Odour: Not available

Odour Threshold: Not available

pH (as supplied): Not available

Melting point / freezing point (degrees C): Melting point 213°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): Freely soluble

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: Diltiazem hydrochloride: 451.02

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; avoid heat.
10.4 Conditions to avoid:	See Section 7.
10.5 Incompatible	See section 7.

materials:	
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION		
Inhalation:	Irritating to mucous membranes and respiratory tract.	
Ingestion:	Potential negative inotrope. Overdose may cause dizziness, headache, nausea, gastrointestinal discomfort, oedema, hypotension, bradycardia, sinoatrial and atroventricular node depression and sinus arrest. Possible hypersensitisation.	
Skin contact:	Has been associated with severe skin reactions including exfoliative dermatitis and epidermal necrolysis.	
Eye contact:	Possible allergic reaction.	
Chronic:	There has been concern that Diltiazem hydrochloride can cause cancer or mutations, but there is not enough data to make an assessment.	
HyperCard®:	Acute toxicity	Irritation
	Not Available	Not Available
Diltiazem hydrochloride:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 560 mg/kg ¹	Not Available
<i>1. * Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances</i>		
Skin corrosion / irritation:		
Can cause an allergic reaction in some people		
Serious eye damage / irritation:		
Can cause an allergic reaction in some people		
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 expected to have reproductive toxicity.
STOT – single exposure:
Not available
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION
12.1 Toxicity
No data available
12.2 Persistence and degradability
No data available
12.3 Bioaccumulative potential
No data available
12.4 Mobility in Soil
No data available
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:	<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> <p>Ensure that the disposal of material is carried out in accordance with</p>



	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

DILTIAZEM HYDROCHLORIDE (33286-22-5) 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
Diltiazem Hydrochloride	33286-22-5	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, Repr. 2, Carc. 2, Acute Tox. 3, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Aquatic Chronic 2, Aquatic Chronic 3, Lact., Eye Dam. 1, Skin Sens. 1	GHS08, GHS06, Dgr, GHS09, GHS05	H351, H311, H301, H315, H335, H411, H362, H318, H317, H360

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

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

The information provided in this Safety Data Sheet has been compiled by Dechra Ltd using a number of different sources, and is correct to the best of its knowledge, information and belief as at the date of its publication. However, Dechra Ltd makes no warranties, express or implied, in relation to the information set out in this Safety Data Sheet, including, without limitation, as to its accuracy or completeness.

The information provided is not a quality specification, and is prepared by way of guidance as to the safe handling, use, processing, storage, transportation, disposal and release of the relevant products referred to. The user is responsible for determining whether or not the product is fit for any particular purpose and/or suitable for the user's proposed method of use and application.

Copyright, 2017, Dechra Ltd. All rights reserved.

Copying and/or downloading of this information for the purpose of properly utilizing Dechra Ltd products is permitted provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from Dechra Ltd, and (2) neither the copy nor the original is resold or otherwise distributed for the purposes of making a profit thereon.