



SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Pardale-V® (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 analgesic therapy in dogs only. The product is indicated for acute pain of traumatic origin, as a complementary treatment in pain associated with other conditions, and post-operative analgesia.
Uses advised against:	<ul style="list-style-type: none"> • Not for human use. • Do not exceed stated dose or duration of treatment. • Do not administer other NSAIDs concurrently or within 24 hours of each other. • Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia or hypersensitivity to the product. • Do not use this product for cats. • Seek veterinary advice if the treated condition does not improve or worsens during treatment, or if any side-effects or adverse reactions are experienced. • NSAIDs can cause inhibition of phagocytosis and hence, in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.
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	
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/v	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 103-90-2 2. Not Available 3. Not Available 4. Not Available	40	Paracetamol	Acute toxicity (oral) Category 4, skin corrosion/irritation Category 2, irritation Category 2, skin Category 1, carcinogenic substance of category 2, STOT-SE (Resp. Irr) Category 3, Chronic aquatic hazard Category 3; H302, H315, H319, H317, H351, H335, H412 ¹
1. 52-28-8 2. 200-137-8 3. Not Available 4. Not Available	0.9	Codeine phosphate hemihydrate	Acute Toxicity (oral) category 3, STOT - SE (narcotics) category 3; H301, H336 ^[1]
N/a	Proprietary	Other ingredients determined not to be hazardous	N/a
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 with fresh water. Seek medical attention if irritation persists, 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 with fresh water and soap. Remove contaminated clothing. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
Inhalation:	Not considered a hazard.
Ingestion:	After accidental ingestion seek medical advice, showing the



	package leaflet or the label to the medical practitioner.
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	
Overdosage with paracetamol can result in sever liver damage and sometimes acute renal tubular necrosis. Prompt treatment with acetylcysteine or methionine is essential.	

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Select extinguishing media suitable for surrounding area; water, dry chemical, carbon dioxide or foam as appropriate.
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:	May be flammable at high temperatures.

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:	Sweep up into suitable sealable containers and wash the affected area with water.
Major Spills:	Sweep up into suitable sealable containers and wash the affected area with water. 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. 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. Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Storage incompatibility:	None 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
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Not Available

Ingredient	Original IDLH	Revised IDLH
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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: Pardale-V®: White, flat tablets with a bevelled edge and a break-line.
 Paracetamol: White crystalline powder
 Codeine phosphate hemihydrate: White crystalline powder

Container: Polypropylene container with a low density polyethylene tamper evident lid, containing 100 or 500 plain white, flat tablets with bevelled edges and a break line on one side and DPL on the other.

Physical state: Solid

Odour: Not available

Odour Threshold: Not available

pH (as supplied): Not available

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 available

Solubility in water and solvents (mg/l): Paracetamol: sparingly soluble
 Codeine phosphate hemihydrate: 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: Paracetamol: 151.2
 Codeine phosphate hemihydrate: 406.4

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:	See Section 7.
10.5 Incompatible materials:	See section 7.
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation:	Not thought to be a hazard.	
Ingestion:	May cause pallor, nausea, vomiting, anorexia, abdominal pain, gastrointestinal irritation and bleeding, insomnia, headache, anxiety, restlessness, vertigo, palpitations, confusion and constipation.	
Skin contact:	May cause skin rashes and other allergic reactions.	
Eye contact:	May cause irritation.	
Chronic:	Overdosage with paracetamol can result in sever liver damage and sometimes acute renal tubular necrosis. Prompt treatment with acetylcysteine or methionine is essential. In therapeutic doses codeine is much less liable than morphine to produce adverse effects. After large doses of codeine, excitement and convulsions may occur.	
Pardale-V®:	Acute toxicity	Irritation
	Not Available	Not Available
Paracetamol:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 2404 mg/kg ¹	Not Available
Codeine phosphate hemihydrate:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 85 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:
Not expected to cause skin corrosion or irritation.
Serious eye damage / irritation:
Not expected to cause serious eye damage or irritation.
Respiratory or skin sensitization:
Not though to cause skin or respiratory sensitization.



SECTION 11: TOXICOLOGICAL INFORMATION

Germ cell mutagenicity:
Not thought to produce any mutagenic potential.
Carcinogenicity:
Not thought to produce any carcinogenic potential.
Reproductive toxicity:
There are no known contraindications for use during pregnancy.
STOT – single exposure:
Not available
STOT–repeated exposure:
Systemic poisoning may occur.
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

	Endpoint	Test Duration (hr)	Species	Value	Source
Paracetamol	LC ₅₀	96	Fish	160mg/L	1
	EC ₅₀	48	Crustacea	9.2mg/L	2
	EC ₅₀	72	Not Available	134mg/L	1
Legend:	1.. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 2. US EPA, Ecotox database - Aquatic Toxicity Data				

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Paracetamol	LOW	LOW

12.3 Bioaccumulative potential

Ingredient	Bioaccumulation
Paracetamol	LOW (LogKOW = 0.46)



12.4 Mobility in Soil	
Ingredient	Mobility
Paracetamol	LOW (KOC = 61.72)
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>Dispose of empty containers and any remaining product in the household refuse.</p> <p>If disposing of bulk material, 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 Hazardous Substances (Disposal) Regulations 2001.</p>
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 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

PARACETAMOL (103-90-2) 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 Cancer Research (IARC)-agents classified by the IARC monographs

CODEINE PHOSPHATE HEMIHYDRATE (52-28-8) 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
Paracetamol	103-90-2	Not Available	01-2119935246-37-XXXX

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4, Aquatic Chronic 3	GHS07, Wng	H302, H412
2	Acute Tox. 4, Skin Irrit. 2, Skin Sens. 1B, Eye Irrit. 2, Aquatic Chronic 3, STOT SE 3, STOT SE 1, Muta. 2, STOT SE 2, STOT RE 2, Skin Sens. 1, Resp. Sens. 1, STOT RE 1, Aquatic Chronic 2, Skin Mild Irrit. 3, Resp. Sens. 1B, Aquatic Chronic 4, Carc. 2	GHS08, Dgr, GHS09	H302, H315, H317, H319, H335, H370, H312, H332, H341, H334, H372, H411, H351

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

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