SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Rapidexon® (2 mg/ml solution for injection).
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:	In horses, cattle, pigs, dogs and cats: Treatment of inflammatory or allergic conditions. In cattle: Treatment of primary ketosis (acetonaemia). Induction of parturition In horses: Treatment of arthritis, bursitis or tenosynovitis.
Uses advised against:	Not for human use. **Pregnant women should not handle this veterinary medicinal product.** **Do not use in known cases of hypersensitivity to the active substance, to corticosteroids and to any other ingredient of the product**. Except in emergency situations, do not use in animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency hyperadrenocorticism, or osteoporosis. Do not use in viral infections during the viraemic stage or in cases of systemic mycotic infections. Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis. Do not administer intra-articularly where there is evidence of fractures, bacterial joint infections and aseptic bone necrosis.
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. 2392-39-4 2. 219-243-0 3. Not Available 4. Not Available	0.2 %	Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 mg	Acute Toxicity (Oral) Category 4, Carcinogenicity Category 2, Reproductive Toxicity Category 2; H302, H351, H361[1]
1. 100-51-6 2. 202-859-9 3. 603-057-00-5 4. 01-2119492630-38-XXXX	1.5 %	Benzyl alcohol	Acute toxicity (inhalation) Category 4, Acute toxicity (oral) category 4; H332, H302[2]
Legend:	*1. Classified by Chemwatch, 2. Classification drawn from EC Directive 1272/2008 - Annex VI*		

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. 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 abundantly with fresh water. Remove contaminated clothing. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
Inhalation:	If fumes or combustion products are inhaled remove from contaminated area. Get medical aid if cough or other symptoms appear.
Ingestion:	Do not induce vomiting. If victim is conscious and alert, give 2-4 cupfuls of milk or water. Get medical aid immediately.
Self-injection:	In case of accidental self-injection, seek medical advice immediately and show the package leaflet 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 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:	Non-combustible. Not considered a significant fire risk, however containers may burn.

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.	
6.3 Methods and material for containment and cleaning up	
Minor Spills:	Absorb solution and place into a suitable disposal container.
Major Spills:	Clean up all spills immediately. Absorb solution and place into a suitable disposal container. 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:	**Pregnant women should not handle the product.** **People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.** Wash exposed areas with soap and water after use of the product. Wash hands after use. Wear suitable protection gloves and clothing when handling the product. Do not allow clothing wet with the material to stay in contact with the skin. 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. Do not freeze. Keep vial in the outer carton. Shelf-life of the veterinary medicinal product as packaged for sale in 50 ml and 100 ml vials: 2 years. Shelf-life of the veterinary medicinal product as packaged for sale in 25 ml vials: 18 months. Shelf-life after first opening the immediate packaging: 28 days.
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: Rapidexon®: A clear colourless solution practically free from particles.
Dexamethasone sodium phosphate: white or almost white, very hygroscopic powder
Container: Vial: 25ml (filled in 30ml vial), 50ml and 100ml; glass type I; quality Ph.Eur., uncoloured. Bromobutyl rubber stopper type I secured with aluminium cap.
Physical state: Liquid
Odour: Odourless
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): Dexamethasone sodium phosphate freely soluble in water
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: Dexamethasone sodium phosphate 516.4
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: as 1% solution in water: 7.5 – 9.5
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:	None known.

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

SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation:	Not expected to cause respiratory tract irritation.	
Ingestion:	May cause gastrointestinal irritation with nausea, vomiting and diarrhoea.	
Skin contact:	Exposure of damaged skin to this material and entry into the blood-stream may be harmful. Skin contact with dexamethasone may damage the health of the individual; systemic effects may result following absorption.	
Eye contact:	Contact may cause transient eye irritation.	
Chronic:	Changes in recordings from specific areas of the CNS, gastrointestinal changes, peritonitis, cardiac changes, elevated blood pressure, respiratory tract changes, foetolethality, foetotoxicity, specific developmental abnormalities (craniofacial, central nervous system, body wall), effects on newborn, maternal effects, reproductive effects recorded with dexamethasone sodium phosphate.	
Rapidexon®:	**Acute toxicity**	**Irritation**
	Not Available	Not Available
Dexamethasone sodium phosphate:	**Acute toxicity**	**Irritation**
	Oral (mouse) LD_{50}: 1800 mg/kg[1]	Not Available
Benzyl alcohol:	**Acute toxicity**	**Irritation**
	Dermal (rabbit) LD_{50}: 2000 mg/kg[1] Inhalation (rat) LC_{50}: >0.004178 mg/L/4h[1] Oral (rat) LD_{50}: 1230 mg/kg[1]	Eye (rabbit): 0.75 mg open SEVERE Skin (man): 16 mg/48h-mild Skin (rabbit):10 mg/24h open-mild
Legend:	*1. Value obtained from manufacturer's SDS*	

Skin corrosion/ irritation:
May cause irritation and systemic effects after absorption.
Serious eye damage/ irritation:
May cause transient eye irritation.
Respiratory or skin sensitization:
Not expected to be a skin sensitizer.

SECTION 11: TOXICOLOGICAL INFORMATION

Germ cell mutagenicity:

Not expected to be a mutagen.

Carcinogenicity:

There has been concern that dexamethasone sodium phosphate can cause cancer or mutations, but there is not enough data to make an assessment.

Reproductive toxicity:

Exposure to the dexamethasone for prolonged periods may cause physical defects in the developing embryo (teratogenesis).
Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy is likely to cause abortion or early parturition in ruminants and may have a similar effect in other species.

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

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Benzyl alcohol	LC_{50}	96	Fish	10mg/L	1
Legend:	*1. US EPA, Ecotox database - Aquatic Toxicity Data*				

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Benzyl alcohol	LOW	LOW

12.3 Bioaccumulative potential

Ingredient	Bioaccumulation
Benzyl alcohol	LOW (LogKOW = 1.1)

12.4 Mobility in Soil	
Ingredient	**Mobility**
Benzyl alcohol	LOW (KOC = 15.66)
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 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

DEXAMETHASONE SODIUM PHOSPHATE (2392-39-4) 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)

BENZYL ALCOHOL (100-51-6) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- EU European Chemicals Agency (ECHA) Community Rolling Action Plan (CoRAP) List of Substances
- European Customs Inventory of Chemical Substances ECICS (English)
- European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)
- European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Dexamethasone sodium phosphate	2392-39-4	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, Carc. 2, Repr. 2	GHS08, Wng	H302, H351, H361
2	Acute Tox. 4, Carc. 2, Repr. 2, Repr. 1B, STOT RE 2, Skin Sens. 1, Lact., Repr. 1A	GHS08, Dgr	H302, H351, H332, H373, H360Df, H317, H362
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The			

most severe classification

Ingredient	CAS number	Index number	ECHA Dossier
Benzyl alcohol	101-51-6	603-057-00-5	01-2119492630-38-XXXX

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, H332
2	Acute Tox. 4, Eye Irrit. 2, Eye Dam. 1, Skin Irrit. 2, Acute Tox. 2, Skin Sens. 1, Acute Tox. 3	GHS05, Dgr, GHS08, GHS09, GHS06	H302, H312, H318, H315, H317, H331

Australia - AICS	Y
Canada - DSL	N (Dexamethasone sodium phosphate)
Canada - NDSL	N (benzyl alcohol)
China - IECSC	N (Dexamethasone sodium phosphate)
Europe - EINEC / ELINCS / NLP	N
Japan - ENCS	N (Dexamethasone sodium phosphate)
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.

Ingredients with multiple CAS numbers:

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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