SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Buprenodale Multidose®, 0.3mg/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:	• Post-operative analgesia in the dog and cat. • Post-operative analgesia, in combination with sedation, in the horse. • Potentiation of the sedative effects of centrally acting agents in the dog and horse.
Uses advised against:	• Do not administer by the intrathecal or peridural route. • The product should not be used pre-operatively in cases of Caesarean section, due to the risk of respiratory depression in the offspring periparturiently, and should only be used post-operatively with special care • As reproductive studies have not been conducted in the target species, use only according to the benefit: risk assessment by the responsible veterinarian. • Do not use in known cases of hypersensitivity to the active substance or any of the excipients.
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]:	No data available
2.2 Label Elements	
Signal Word:	No data available
Hazard Statement(s)	
No data available	
Additional Statement(s)	
None	
Precautionary Statement(s) Prevention:	
P270	Do not eat, drink or smoke when using this product.
Precautionary Statement(s) Response:	
P330	Rinse mouth.
Precautionary Statement(s) Storage:	
P405	Store locked up
Precautionary Statement(s) Disposal:	
P501	Dispose of contents / packaging according to local regulations
2.3 Other Hazard Information N/a	

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. 53152-21-9 2. 258-396-8 3. Not Available 4. Not Available	0.324%	Buprenorphine 0.3mg as buprenorphine hydrochloride 0.324mg	Acute Toxicity (Oral) Category 4, Reproductive Toxicity Category 2, Specific target organ toxicity - single exposure Category 3 (narcotic effects), Specific target organ toxicity - repeated exposure Category 2; H302, H361, H336, H373 [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:	Following eye contamination, wash thoroughly with cold running water. Seek medical advice if irritation persists and show the package leaflet or the label to the medical practitioner.
Skin contact:	Following skin contact, wash thoroughly with cold running water. Seek medical advice if irritation persists and show the package leaflet or the label to the medical practitioner.
Inhalation:	Due to physical form of this product, inhalation exposure is unlikely. If accidentally inhaled, remove from exposure and seek medical attention if irritation occurs, showing the package leaflet or the label to the medical practitioner.
Ingestion:	Remove material and flush mouth with water. Seek medical attention: treatment is symptomatic and includes replacement of fluid and electrolytes. Show the package leaflet or the label to the medical practitioner.
Self-injection:	As buprenorphine has opioid-like activity, care should be taken to avoid accidental self-injection. In case of accidental self-injection or ingestion, seek medical advice immediately and show 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

Treat symptomatically.
Advice to doctors: Naloxone may be of benefit in reversing reduced respiratory rate and respiratory stimulants such as Doxapram are also effective in man. Because of the prolonged duration of effect of buprenorphine in comparison to such drugs, they may need to be administered repeatedly or by continuous infusion. Volunteer studies in man have indicated that opiate antagonists may not fully reverse the effects of buprenorphine.

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Water spray, carbon dioxide, dry chemical and foam, as appropriate for surrounding fire and materials.
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:	None known.

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:	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite.
Major Spills:	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent, by any means available, spillage from entering drains or water course. Large spills should be collected into an appropriate container for waste disposal.

SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	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:	Protect from light. Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. Shelf-life after first opening the vial: 28 days.
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 (EU)	
Not Available	
PREDICTED NO EFFECT LEVEL - PNEC (EU)	
Not Available	
OCCUPATIONAL EXPOSURE LIMITS (OEL)	
INGREDIENT DATA:	
Not Available	
EMERGENCY LIMITS:	
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: Buprenodale Multidose®: Clear, colourless solution
Container: Cardboard carton containing a 10 ml clear Type I glass vial with a FluroTec coated bromobutyl rubber stopper and aluminium seal.
Physical state: Solution for injection
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Buprenorphine hydrochloride melting point: 265-271°C
Initial boiling point and boiling range: Not available
Flash Point: In water – no flash point.
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): Buprenorphine hydrochloride in water: slightly 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: Not available
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. Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions:	The product is not considered to be hazardous if used as per instructions. Hazardous polymerisation will not occur.
10.4 Conditions to avoid:	Avoid excessive heat.

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

SECTION 11: TOXICOLOGICAL INFORMATION		
Inhalation:	Due to physical form of this product, inhalation exposure is unlikely.	
Ingestion:	May cause irritation if ingested.	
Skin contact:	The product may produce skin irritation in some persons**.**	
Eye contact:	The product may produce eye irritation in some persons**.**	
Self-injection:	As buprenorphine has opioid-like activity, care should be taken to avoid accidental self-injection. In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.	
Chronic:	Naloxone may be of benefit in reversing reduced respiratory rate and respiratory stimulants such as Doxapram are also effective in man. Because of the prolonged duration of effect of buprenorphine in comparison to such drugs, they may need to be administered repeatedly or by continuous infusion. Volunteer studies in man have indicated that opiate antagonists may not fully reverse the effects of buprenorphine.	
Buprenodale Multidose®:	**Acute toxicity**	**Irritation**
	Not Available	Not Available
Buprenorphine hydrochloride:	**Acute toxicity**	**Irritation**
	Oral (rat) LD_{50}: 80 mg/kg*e[1]	Eye: moderate Skin: moderate
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 available		
Serious eye damage/irritation:		
Not available		
Respiratory or skin sensitization:		
Not available		

SECTION 11: TOXICOLOGICAL INFORMATION
Germ cell mutagenicity:
Not available
Carcinogenicity:
Not available
Reproductive toxicity:
Laboratory studies in rats have not produced any evidence of a teratogenic effect. However, these studies have shown post-implantation losses and early foetal deaths. These may have resulted from a reduction in parental body condition during gestation and in post-natal care owing to sedation of the mothers.
STOT – single exposure:
Not available
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION
12.1 Toxicity
No data Available
DO NOT discharge into sewer or waterways.
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
No data Available
12.6 Other adverse effects
No data 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

BUPRENORPHINE HYDROCHLORIDE (53152-21-9) 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)

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable-: 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	**CAS number**	**Index Number**	**ECHA Dossier**
Buprenorphine hydrochloride	53152-21-9	Not Available	Not Available
Harmonization (C&L Inventory)	**Hazard Class and Category Code(s)**	**Pictograms Signal Word Code(s)**	**Hazard Statement Code(s)**
1	Acute Tox. 4, Repr. 2	GHS08, Wng	H302, H361
2	Acute Tox. 4, Repr. 2, Skin Sens. 1, Resp. Sens. 1, STOT SE 3, Lact., STOT SE 1, Acute Tox. 3, Acute Tox. 2, Repr. 1B, Eye Irrit. 2, STOT RE 2	GHS08, Dgr, GHS06	H317, H334, H336, H362, H370, H330, H300, H310, H360D, H319, H373

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

ustralia - AICS	Y
Canada - DSL	N (buprenorphine hydrochloride)
Canada - NDSL	N (buprenorphine hydrochloride)
China - IECSC	N (buprenorphine hydrochloride)
Europe - EINEC / ELINCS / NLP	Y

Japan - ENCS	N (buprenorphine hydrochloride)
Korea - KECI	N (buprenorphine hydrochloride)
New Zealand - NZIoC	Y
Philippines - PICCS	N (buprenorphine hydrochloride)
USA - TSCA	N (buprenorphine 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

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