SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Osphos® (Clodronate Injection)
Synonyms:	Not Available
Proper Shipping name:	Not applicable
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	Solution for injection for the control of clinical signs associated with the bone resorptive processes of navicular syndrome in horses.
Uses advised against:	Not for human use. Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption.
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
Website:	www.dechra.com
Email:	Not available
New Zealand Supplier:	RxVet Ltd
Address:	Unit 15 2-4 Northpoint Street Plimmerton Porirua 5026
Telephone:	0800 479 838
Fax:	04 974 7793
Website:	www.rxvet.co.nz

Email:	info@rxvet.co.nz
1.4 Emergency Telephone Numbers	
Dechra (US):	866-933-2472
New Zealand National Poisons Center:	0800 764 766 [0800 POISON], 24 hour service
SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
Classification[1]:	Acute Toxicity (Oral) Category 5, Eye Irritation Category 2B, Reproductive Toxicity Category 2
Legend:	*1. Classified by Chemwatch*
2.2 Label Elements	
GHS Label Elements:	
Signal Word:	WARNING
Hazard statement(s):	
H303	May be harmful if swallowed.
H320	Causes eye irritation.
H361	Suspected of damaging fertility or the unborn child.
Precautionary Statement(s) Prevention:	
P201	Obtain special instructions before use.
P264	Wash all exposed external body areas thoroughly after handling.
P281	Use personal protective equipment as required.
Precautionary Statement(s) Response:	
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Precautionary Statement(s) Storage:	
P405	Store locked up.
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/container in accordance with local regulations.

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

CAS No	% Weight	Name	Indication
88416-50-6	6	Disodium Clodronate Tetrahydrate	Can cause gastrointestinal disturbances. In rat studies, Disodium Clodronate is shown to have detrimental effects during pregnancy.
Not available	Proprietary	Other ingredients determined not to be hazardous	Not applicable

SECTION 4: FIRST AID MEASURES

NZ Poisons Centre 0800 POISON (0800 764 766) | NZ Emergency Services: 111

4.1 Description of first aid measures

Eye contact:	Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Skin contact:	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
Ingestion:	Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered. If swallowed, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove material and give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
Self-injection:	Care should be taken when handling the product to avoid self-injection, especially by pregnant women. Read the package leaflet before use for full instructions and user warnings.

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 Not applicable	
SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Select extinguishing media suitable for surrounding area
Unsuitable:	There is no restriction on the type of extinguisher which may be used
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known
5.3 Special protective actions for fire-fighters:	
Firefighting:	Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses DO NOT approach containers suspected to be hot. Equipment should be thoroughly decontaminated after use.
Fire / explosion hazard:	Non-combustible. Not considered a significant fire risk, however containers may burn. May emit poisonous fumes. May emit corrosive fumes.
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	
See section 12	
6.3 Methods and material for containment and cleaning up Spills are unlikely due to the nature of the product and how it is packaged	
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. Place in a suitable, labelled container for waste disposal.
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.

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. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Observe manufacturer's storage and handling recommendations.

7.2 Conditions for safe storage, including any incompatibilities

Safe Storage:	Do not store above 25ºC. Discard unused material. Check that containers are clearly labelled. Keep out of the reach and sight of children. Once broached use immediately. The diluted infusion solution may be stored for up to 24 hours at room temperature. Shelf life of the veterinary medicinal product as packaged for sale: 2 years. Keep the container in the outer carton. Stored in a cardboard carton containing a clear 15ml Type I glass vial with a grey siliconised rubber stopper and aluminium seal.
Storage incompatibility:	No known incompatibilities.

7.3 Specific end uses

Not available

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA:						
Source	**Ingredient**	**Material Name**	**TWA**	**STEL**	**Peak**	**Notes**
New	Sodium	Sodium	Not	Not	2 mg/m3	Not

INGREDIENT DATA:						
Zealand Workplace Exposure Standards (WES)	Hydroxide	Hydroxide	Available	Available		Available

EMERGENCY LIMITS:				
Ingredient	**Material Name**	**TEEL-1**	**TEEL-2**	**TEEL-3**
Sodium Hydroxide	Sodium Hydroxide	Not Available	Not Available	Not Available

Ingredient	**Original IDLH**	**Revised IDLH**
Disodium Clodronate Tetrahydrate	Not Available	Not Available
Sodium Hydroxide	250 mg/m^3	10 mg/m^3
Water	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

Recommended Material(s)

Glove Selection Index
Glove selection is based on a modified presentation of the:
***"*Forsberg Clothing Performance Index".**
The effect(s) of the following substance(s) are taken into account in the ***computer-generated*** selection;

INGREDIENT DATA:

Osphos

Material	CPI
BUTYL	C
NAT+NEOPR+NITRILE	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NEOPRENE/NATURAL	C
NITRILE	C
NITRILE+PVC	C
PE	C
PE/EVAL/PE	C
PVA	C
PVC	C
SARANEX-23	C
SARANEX-23 2-PLY	C
TEFLON	C
VITON	C
VITON/CHLOROBUTYL	C

* CPI - Chemwatch Performance Index
A: Best Selection
B: Satisfactory; may degrade after 4 hours continuous immersion
C: Poor to Dangerous Choice for other than short term immersion
NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -
* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise
be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

8.3 Environmental exposure controls
Not Available

INGREDIENT DATA:

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Osphos: Clear and colourless aqueous solution
Disodium Clodronate Tetrahydrate: White crystalline powder
Physical state: Liquid
Odour: Not available
Odour Threshold: Not available
pH (as supplied): 3.8 – 4.5
Melting point / freezing point (degrees C): Not available
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): Freely soluble (water)
Chloroform – Practically insoluble
Benzene – Practically insoluble
Ethylether – Practically insoluble
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: Disodium Clodronate: 360.93 (anhydrous: 288.9)
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

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Unstable in the presence of incompatible materials. 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.

INGREDIENT DATA:	
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:	The material can cause respiratory irritation in some persons.	
Ingestion:	Accidental ingestion of the material may be damaging to the health of the individual.	
Skin contact:	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). The acids and salts of ATMP, HEDP and DTPMP have a low level of acute skin toxicity. ATMP acid and its salts, in testing, were found to be practically non-toxic.	
Eye contact:	Can cause eye irritation in some persons. The phosphonic acid compounds, ATMP, HEDP, DTPMP and their salts vary in their potential to irritate the eye, from virtually non-irritating to severely irritating with irreversible effects.	
Chronic:	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Exposure to small quantities may induce hypersensitivity reactions characterised by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic oedema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur.	
Self-injection:	The most common adverse effects include gastrointestinal disturbances. In general, clodronate is well tolerated following intravenous, intramuscular or oral administration.	
Osphos:	**Toxicity**	**Irritation**
	Not Available	Not Available

INGREDIENT DATA:			
Disodium Clodronate Tetrahydrate:	**Toxicity**	**Irritation**	
	Oral (mouse) LD50: >2000 mg/kg[2] The most common adverse effects include gastrointestinal disturbances, including nausea, and vomiting and diarrhoea, following oral administration of clodronate which can be alleviated by dividing or lowering the dosage. In most cases, these effects are mild and transient. In general, clodronate is well tolerated following intravenous, intramuscular or oral administration.	Not available	
Sodium Hydroxide:	**Toxicity**	**Irritation**	
	Oral (rabbit) LD50: 325 mg/kg[1]	Eye (rabbit): 0.05 mg/24h SEVERE Eye (rabbit):1 mg/24h SEVERE Eye (rabbit):1 mg/30s rinsed-SEVERE Skin (rabbit): 500 mg/24h SEVERE	
Water:	**Toxicity**	**Irritation**	
	Oral (rat) LD50: >90000 mg/kg[2]	Not Available	
1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances*			
a) Acute toxicity:	Not classified for acute toxicity, based on available studies results on oral and dermal routes of exposure.	**f) Carcinogenicity:**	Not available

INGREDIENT DATA:			
b) Skin corrosion/ irritation:	Low pH (<2) would predict that ATMP acid should be severely irritant or corrosive to skin as well as eyes, however available existing animal data indicating non-classification take precedence in accordance with EU regulation (EC) 1272/2008 criteria ATMP acid and some of its sodium salts may cause corrosion to metals to varying degrees dependent upon the	**g) Reproductive toxicity:**	In rat studies, Disodium Clodronate is shown to have detrimental effects during pregnancy.
c) Serious eye damage/ irritation:	Sodium Hydroxide may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.	**h) STOT – single exposure:**	Not available
d) Respiratory or skin sensitization:	Not Available	**i) STOT–repeated exposure:**	Not available
i) Germ cell mutagenicity:	Not available	**j) Aspiration hazard:**	Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Sodium Hydroxide	LC50	96	Fish	4.16158mg/L	1
Sodium Hydroxide	EC50	96	Algae or other aquatic plants	1034.10043mg/L	1
Sodium Hydroxide	EC50	384	Crustacea	27901.643mg/L	1
Sodium Hydroxide	NOEC	96	Fish	56mg/L	2
			Legend:	*1. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 2. 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
Sodium Hydroxide	LOW	LOW
Water	LOW	LOW

12.3 Bioaccumulative potential

Ingredient	Bioaccumulative Potential
Sodium Hydroxide	LOW (LogKOW = -3.8796)
Water	LOW (LogKOW = -1.38)

12.4 Mobility in Soil

Ingredient	Mobility
Sodium Hydroxide	LOW (KOC = 14.3)
Water	LOW (KOC = 14.3)

12.5 Results of PBT and vPvB assessment
Not Applicable

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. A Hierarchy of Controls seems to be common - the user should investigate: Reduction Reuse Recycling Disposal (if all else fails) Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.

SECTION 14: TRANSPORT INFORMATION		
Labels required:		
Marine pollutant:	NO	
Hazchem:	Not Applicable	
Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
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
	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): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
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): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
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	

SECTION 15: REGULATORY INFORMATION

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

This substance is to be managed using the conditions specified in an applicable Group Standard

HSR Number	Group Standard
HSR100757	Veterinary Medicine (Limited Pack Size, Finished Dose) Group Standard 2012

Registered pursuant to the ACVM Act 1997 No A11429
Restricted Veterinary Medicine

DISDOIUM CLODRONATE TETRAHYDRATE (88416-50-6) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

New Zealand Inventory of Chemicals (NZIoC)

SODIUM HYDROXIDE (1310-73-2) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals
New Zealand Workplace Exposure Standards (WES)
New Zealand Inventory of Chemicals (NZIoC)

Location Test Certificate
Subject to Regulation 55 of the Hazardous Substances (Classes 1 to 5 Controls) Regulations, a location test certificate is required when quantity greater than or equal to those indicated below are present.

Hazard Class	Quantity beyond which controls apply for closed containers	Quantity beyond which controls apply when use occurring in open containers
Not Applicable	Not Applicable	Not Applicable

Approved Handler
Subject to Regulation 56 of the Hazardous Substances (Classes 1 to 5 Controls) Regulations and Regulation 9 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations, the substance must be under the personal control of an Approved Handler when present in a quantity greater than or equal to those indicated below.

Class of substance	Quantities
Not applicable	Not applicable

Refer group Standards for further information

National Inventory	Status
Australia - AICS	N (clodronic acid, sodium salt)
Canada - DSL	N (clodronic acid, sodium salt)
Canada - NDSL	N (clodronic acid, sodium salt, water, sodium hydroxide)
China - IECSC	N (clodronic acid, sodium salt)
Europe - EINEC / ELINCS / NLP	Y

Japan - ENCS	N (clodronic acid, sodium salt, water)
Korea - KECI	N (clodronic acid, sodium salt)
New Zealand - NZIoC	N (clodronic acid, sodium salt)
Philippines - PICCS	N (clodronic acid, sodium salt)
USA - TSCA	N (clodronic acid, sodium salt)
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)*

15.2 Chemical Safety Assessment
Not applicable

SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS, OSHA and ECHA.

Ingredients with multiple CAS numbers:

Name	CAS Number
Disodium Clodronate Tetrahydrate	88416-50-6, 22560-50-5
Sodium Hydroxide	1310-73-2, 12200-64-5

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 SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Prepared by DECHRA LTD on the basis of the best available data. No representation is given that the information provided is complete in all respects.

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.