Version No: 1 Page 1 of 22



SECTION 1: IDENTIFICATION								
1.1 Product identifier								
Product name:	Osphos® (60 mg/ml Solution for 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 o	f the substance or mixture							
Registered company name (UK):	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							
Nom du distributeur [(Canada):	Dechra Veterinary Products							
Adresse :	Dechra Veterinary Products 1 Holiday Ave, tour Est, Suite 345 Pointe-Claire, QC H9R 5N3 Canada							
Téléphone :	1 855 332-9334							
Site Web :	www.dechra.ca							
Courriel :	Non disponible							
1.4 Numéros de téléphone d	l'urgence							
Dechra (ÉU.) :	1 866 933 2472							
Dechra (CA) :	1 855 332-9334							

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017

Version No: 1 Page 2 of 22



SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes (EU).

Considered a Hazardous Substance by the 2012 OSHA Hazard Communication Standard (29 CFR 1910 1200). Not classified as Dangerous Goods for transport purposes (US)

	as Dangerous Goods for transport purposes (US).					
DSD Classification (EU):	In case of mixtures, classification has been prepared by following DPD (Directive 1999/45/EC) and CLP Regulation (EC) No 1272/2008 regulations					
DPD Classification (EU)1:	R63(3): Possible risk of harm to the unborn child					
Legend:	1. Classified by Chemwatch					
Classification according to regulation (EC) No 1272/2008 [CLP] (EU) ¹ :	H361: Reproductive Toxicity Category 2					
Legend:	1. Classified by Chemwatch					
Classification (US):	Eye Irritation Category 2B, Reproductive Toxicity Category 2					
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.					

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017

Version No: 1 Page 3 of 22



Precautionary Statement(s) Response:						
P312 Call a POISON CENTER or doctor/physician if you feel unw						
P308 + P313 IF exposed or concerned: Get medical advice/attention.						
P337 + P313	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

Ingestion may produce health damage*
Cumulative effects may result following exposure*
May produce discomfort of the eyes*

REACH (EU) Article 57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

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 3.3.Index Number 4.4.REACH Number	% Weight	Name	Classification according to directive 67/548/EEC [DSD] (EU)	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
 22560-50-5 245-078-9 Not Available Not Available 	6	Clodronic Acid (51mg/ml) as Disodium Clodronate (60mg/ml)	R53, R63(3) ¹	Reproductive Toxicity Category 2, Chronic Aquatic Hazard Category 4; H361, H413 ¹
1. 1310-73-2 2. 215-185-5 3. 011-002-00-6 4. 01-2119457892- 27-XXXX, 01- 2119982981-22- XXXX	<0.1	Sodium Hydroxide	R35 ²	Skin Corrosion/Irritation Category 1A; H314 ³

Version No: 1 Page 4 of 22



Legend:	1. Classified by Chemwatch; 2. Classification drawn from EC Directive
	67/548/EEC - Annex I; 3. Classification drawn from EC Directive 1272/2008 –
	Annex VI

SECTION 4: FIRST AID MEASURES						
4.1 Description of first a	id 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						

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017

Version No: 1 Page 5 of 22



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 arisin	g from the substance or mixture					
Fire incompatibility:	None known					
5.3 Special protective acti	ons 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
SECTION	J. ACCIDENTAL	NELLAGE MEAGUNES

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.

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017

Version No: 1 Page 6 of 22



SECTION 7: HANDLING AND STORAGE							
7.1 Precautions for safe h	andling						
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.						
Other Information:	Do not store above 25°C. Discard unused material. Keep out of the reach and sight of children.						
7.2 Conditions for safe sto	orage, including any incompatibilities						
Suitable Container:	Keep the container in the outer carton. Check that containers are clearly labelled. 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.						
Storage incompatibility:	No known incompatibilities.						
7.3 Specific end uses							

8.1 Control parameters

DERIVED NO EFFECT LEVEL - DNEL (EU)

Not Available

Not available

PREDICTED NO EFFECT LEVEL - PNEC (EU)

Not Available

OCCUPATIONAL EXPOSURE LIMITS (OEL)

Issue Date: 09/2017 Version No: 1 Page 7 of 22



INGREDIENT D	ATA (E	U):									
Source	Ingred	edient Materia		al	TWA	S	STEL		Peak		Notes
UK Workplace Exposure Limits (WELs)			Sodium Hydroxide		Not Available		2 mg/m ³		Not Available		Not Available
INGREDIENT D	ATA (U	S):									
Source	Ingred		Material Name		TWA	S	STEL		Peak		Notes
US OSHA Permissible Exposure Levels (PELs) - Table Z1				n kide	2 mg/m3		Not Available		Not Available		Not Available
US ACGIH Threshold Limit Values (TLV)			Sodium Hydroxide		Not Available		Not Available		2 mg/m3		TLV® Basis: URT, eye, & skin irritation
US NIOSH Recommended Exposure Limits (RELs)	Hydroxide				Not Available	1	Not Available		2 mg/m3		Not Available
EMERGENCY L	IMITS (EU/US	S):						•		
Ingredient		Mater Name		al TEEL-1			TEEL-2			TEEL-3	
Sodium Hydroxid	de	Sodiu Hydro				Not Available		Not Available			
Ingredient		•	Origi	Original IDLH		Revised IDLH					
Clodronic acid (Disodium Clodronate)		Not A	Not Available			Not Available					
Sodium Hydroxide		250 n	250 mg/m ³			10 mg/m ³					
Water		Not A	Not Available Not Available								
8.2 Exposure co	ontrols		•					•			
Appropriat	Appropriate engineering The basic types of engineering controls are: controls: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.						involv	e ch	nanging t	he w	

Issue Date: 09/2017

Version No: 1 Page 8 of 22



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 of See Section 12	controls

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017 Version No: 1 Page 9 of 22



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Osphos: Clear and colourless aqueous solution

Clodronic acid (Disodium Clodronate): White crystalline powder

Container: cardboard carton containing a clear 15ml Type I glass vial with a grey siliconised

rubber stopper and aluminium seal.

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

10: REACTIVITY AND STABILITY		
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	The product is not considered to be hazardous if used as per	

Issue Date: 09/2017 Version No: 1 Page 10 of 22



hazardous reactions:	instructions. Hazardous polymerisation will not occur.	
10.4 Conditions to avoid:	See Section 7.	
10.5 Incompatible materials:	See section 7.	
10.6 Hazardous decomposition:	See Section 5.	

SECTION 11: TOXICOL	ECTION 11: TOXICOLOGICAL INFORMATION			
Inhalation:	The material can cause resp	iratory irritation in some persons.		
Ingestion:	Accidental ingestion of the mof the individual.	naterial may be damaging to the health		
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		

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017 Version No: 1 Page 11 of 22



SECTION 11: TOXICOLOGICAL INFORMATION				
Clodronic acid	Acute toxicity	Irritation		
(Disodium Clodronate):	Oral (mouse) LD ₅₀ : >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) LD ₅₀ : 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) LD ₅₀ : >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

Skin corrosion/ irritation:

Not Available

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.

Respiratory or skin sensitization:

Not Available

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017 Version No: 1 Page 12 of 22



SECTION 11: TOXICOLOGICAL INFORMATION
Germ cell mutagenicity:
Not Available
Carcinogenicity:
Not Available
Reproductive toxicity:
In rat studies, Disodium Clodronate is shown to have detrimental effects during pregnancy.
STOT – single exposure:
Not Available
STOT-repeated exposure:
Not Available
Aspiration hazard:

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not Available

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Sodium Hydroxide	LC ₅₀	96	Fish	4.16158mg/L	1
Sodium Hydroxide	EC ₅₀	96	Algae or other aquatic plants	1034.10043mg/L	1
Sodium Hydroxide	EC ₅₀	384	Crustacea	27901.643mg/L	1
Sodium Hydroxide	NOEC	96	Fish	56mg/L	2
		_	. =====================================	(0.10.(0.01.0)	

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				

Issue Date: 09/2017

Version No: 1 Page 13 of 22



Ingredient	Bioaccumulative Potential		
Sodium Hydroxide	LOW (LogKOW = -3.8796)		
Water	LOW (LogKOW = -1.38)		
12.4 Mobility in So	, il		
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 Not Available	12.6 Other adverse effects Not Available		

SECTION 13: DISP	SECTION 13: DISPOSAL CONSIDERATIONS		
13.1 Waste treatme	ent methods		
	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 Products Regulations (Canada, 2015).		
Waste Treatment Options:	Not Available		
Sewage Disposal Options:	Not Available		

Issue Date: 09/2017 Version No: 1 Page 14 of 22



SECTION 14: TRANS	SPORT INFORMATION		
Labels required:			
Marine pollutant:	NO		
Hazchem:	Not Applicable		
Land transport (EU: DANGEROUS GOOD		REGULATED FOR TRANSPORT OF	
14.1 UN Number	N/a		
14.2 UN Proper Shipping Name	N/a		
14.3 Transport	Class	N/a	
hazard class(es)	Sub risk	N/a	
14.4 Packing group	N/a		
14.5 Environmental hazards	N/a		
14.6 Special precautions for	Special provisions	N/a	
user	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-IDANGEROUS GOOD		ULATED FOR TRANSPORT OF	
14.1 UN Number	N/a		
14.2 UN Proper Shipping Name	N/a		
14.3 Transport	ICAO/IATA Class	N/a	
hazard class(es)	ICAO / IATA Sub risk	N/a	
	ERG Code	N/a	
14.4 Packing group	N/a		
14.5 Environmental hazards	N/a		
	Special provisions	N/a	
precautions for user	Cargo only packing instructions	N/a	

Issue Date: 09/2017 Version No: 1 Page 15 of 22



MARPOL73/78 and the IBC Code Inland waterways tra DANGEROUS GOOD		REGULATED FO	OR TRANSPORT OF
14.7 Transport in bulk according to Annex II of	N/a		
usei	Limited quantities	N/a	·
precautions for user	Special provisions	N/a	•
	EMS Number	N/a	
14.5 Environmental hazards	N/a		
14.4 Packing group	N/a		
hazard class(es)	IMDG Sub risk		
14.3 Transport	IMDG Class	N/a	
14.2 UN Proper Shipping Name	N/a		
14.1 UN Number	N/a		
Sea transport (IMDG DANGEROUS GOOD		OT REGULATED	FOR TRANSPORT OF
bulk according to Annex II of MARPOL73/78 and the IBC Code	TV a		
14.7 Transport in	qty/pack		
	Passenger and cargo	o N/a	•
	Passenger and cargorimited quantity packing instructions	o N/a	
	Passenger and cargo maximum qty/pack	N/a	
	Passenger and cargo packaging instruction		
	Cargo only maximun qty/pack	n N/a	

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017 Version No: 1 Page 16 of 22



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	
	Classification Code	N/a
precautions for user	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

CLODRONIC ACID (DISODIUM CLODRONATE) (22560-50-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017

Version No: 1 Page 17 of 22



SODIUM HYDROXIDE (1310-73-2) 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)
- European Union (EU) Annex I to Directive 67/548/EEC on Classification and Labelling of Dangerous Substances - updated by ATP: 31
- European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures Annex VI
 - UK Workplace Exposure Limits (WELs)
 - US Alaska Limits for Air Contaminants
 - US California OEHHA/ARB Acute Reference Exposure Levels and Target Organs (RELs)
 - US California Permissible Exposure Limits for Chemical Contaminants
 - US Hawaii Air Contaminant Limits
 - US Idaho Limits for Air Contaminants
 - US Massachusetts Right To Know Listed Chemicals
 - US Michigan Exposure Limits for Air Contaminants
 - US Minnesota Permissible Exposure Limits (PELs)
 - US Oregon Permissible Exposure Limits (Z-1)
 - US Pennsylvania Hazardous Substance List
 - US Rhode Island Hazardous Substance List
 - US Tennessee Occupational Exposure Limits Limits For Air Contaminants
 - US Vermont Permissible Exposure Limits Table Z-1-A Final Rule Limits for Air Contaminants
 - US Vermont Permissible Exposure Limits Table Z-1-A Transitional Limits for Air Contaminants
 - US Washington Permissible exposure limits of air contaminants
 - US Washington Toxic air pollutants and their ASIL, SQER and de minimis emission values
 - US Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants
 - US ACGIH Threshold Limit Values (TLV)
 - US CWA (Clean Water Act) List of Hazardous Substances
 - US NIOSH Recommended Exposure Limits (RELs)
 - US OSHA Permissible Exposure Levels (PELs) Table Z1
 - US Toxic Substances Control Act (TSCA) Chemical Substance Inventory

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017 Version No: 1 Page 18 of 22



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, Commission Regulation (EU) 2015/830, Regulation (EC) No 1272/2008 and their amendments.

FEDERAL REGULATIONS:

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 Hazard Categories

Immediate (acute) health hazard	Yes
Delayed (chronic) health hazard	Yes
Fire hazard	No
Pressure hazard	No
Reactivity hazard	No

US. EPA Cercla Hazardous Substances and Reportable Quantities (40 CFR 302.4)

Name	Reportable Quantity in Pounds (lb)	Reportable Quantity in kg
Sodium hydroxide	1000	454

STATE REGULATIONS:

US. CALIFORNIA PROPOSITION 65

None reported

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Clodronic acid (Disodium Clodronate)	22560-50-5	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	STOT RE 2, Aquatic Chronic 2	GHS09, GHS08, Wng	H373
2	STOT RE 2, Aquatic Chronic 2	GHS09, GHS08, Wng	H373
1	Acute Tox. 4, Repr. 2, Aquatic Chronic 3	GHS07, GHS08, Wng	H302, H332, H361
2	Acute Tox. 4, Repr. 2, Aquatic Chronic 3	GHS08, Wng	H302, H332, H361

Harmonization Code 1 =The most prevalent classification.

Harmonization Code 2 = The most severe classification

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017 Version No: 1 Page 19 of 22



Ingredient	CAS Number	Index Number	ECHA Dossier
Sodium Hydroxide	1310-73-2		01-2119457892-27- XXXX, 01-2119982981- 22-XXXX

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Index Number	ECHA Dossier
1	Skin Corr. 1A	GHS05, Dgr	H314
2	Skin Corr. 1A	GHS05, Dgr	H314
1	Skin Corr. 1A	GHS05, Dgr	H314
2	Met. Corr. 1, Skin Corr. 1A, Eye Dam. 1, Acute Tox. 4, Skin Corr. 1B, STOT SE 3, Eye Irrit. 2, Aquatic Chronic 3, STOT SE 1, Skin Corr. 1C, Aquatic Acute 3	GHS05, Dgr, GHS06, GHS08	H290, H314, H312, H318, H335, H370, H302
1	Skin Corr. 1A	GHS05, Dgr	H314
2	Skin Corr. 1A	GHS05, Dgr	H314, H302

Harmonization Code 1 = The most prevalent classification.

Harmonization Code 2 = The most severe classification

Ingredient	CAS Number	Index Number	ECHA Dossier
Water	7732-18-5	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	GHS06, GHS05, Dgr, GHS02, Wng	H301, H226, H314
2	Acute Tox. 3, Skin Corr. 1A, Acute Tox. 2, Flam. Liq. 3	GHS06, GHS05, Dgr, GHS02, Wng	H301, H226, H314

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

National Inventory	Status
Australia - AICS	N (clodronic acid, sodium salt)
Canada - DSL	N (clodronic acid, sodium salt)

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017 Version No: 1 Page 20 of 22



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)

SECTION 16: OTHER INFORMATION

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

Full text Risk and Hazard codes:

H226	Flammable liquid and vapour
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H332	Harmful if inhaled
H335	May cause respiratory irritation
H370	Causes damage to organs
H373	May cause damage to organs through prolonged or repeated exposure
H413	May cause long lasting harmful effects to aquatic life

R35	Causes severe burns
R53	May cause long-term adverse effects in the aquatic environment

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017

Version No: 1 Page 21 of 22



Ingredients with multiple CAS numbers:

ingrediente with mattiple et le namberer	
Name	CAS Number
Clodronic acid (Disodium Clod	ronate) 22560-50-5, 88416-50-6
Sodium Hydroxide	1310-73-2, 12200-64-5

Relevant risk statements are found in section 2.1

Indication(s) of danger Xn	
indication(s) of danger An	

S02	Keep out of reach of children
S23	Do not breate gas/fumes/vapour/spray
S35	This material and its container must be disposed of in a safe way
S36	Wear suitable protective clothing
S37	Wear suitable gloves
S40	To clean the floor and all objects contaminated by this material, use water and detergent
S46	If swallowed, seek medical advice immediately and show this container or label
S53	Avoid exposure – obtain special instructions before use
S56	Dispose of this material and its container at hazardous or special waste collection point

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

NFPA 704 diamond (US):



Blue = Health, Red = Fire, Yellow = Reactivity, White = Special (Oxidizer or water reactive substances)

Product Name: Osphos® (60mg/ml Solution for Injection)

Issue Date: 09/2017

Version No: 1 Page 22 of 22



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 Limited 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 Limited 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 Limited. All rights reserved.

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