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SECTION 1: IDENTIFICATION			
1.1 Product identifier			
Product name:	Vitbee® (0.025% or 0.1% 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:	As an aid in raising Vitamin B12 levels in sheep, foals and calves. For use in the treatment of Vitamin B12 deficiency, and for poor growth rates and general unthriftiness in young animals when associated with the above deficiency.		
Uses advised against:	Not for human use. Do not give by the intravenous route.		
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 N	1.4 Emergency Telephone Numbers		
	+44 (0) 1756 791311		

SECTION 2: HAZARDS IDEN	ITIFICATION
2.1 Classification of the sub	ostance or mixture
DSD Classification (EU):	Not Available
DPD Classification:	Not Available
Classification according to	Not Available

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regulation (EC) No 1272/2008 [CLP] (EU) ¹ :	
2.2 Label Elements	
Signal Word:	Not Available
Hazard Statement(s)	
Not Available	
Additional Statement(s)	
None	
Precautionary Statement(s)	Prevention:
Not Available	
Precautionary Statement(s)	Response:
Not Available	
Precautionary Statement(s)	Storage:
Not Available	
Precautionary Statement(s)	Disposal:
Not Available	

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

2.3 Other Hazard Information

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. 68-19-9 2. 200-680-0 3. Not Available 4. 01-2120088037-53- XXXX	0.025 – 0.1	Cyanocobalamin (Vitamin B12)	Not Applicable
N/a	Proprietary	Other ingredients determined not to be	N/a

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		hazardous	
Legend:	1. Classified by C	Chemwatch	

4.1 Description of first a	aid measures
•	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 label to the medical practitioner.
Skin contact:	In case of accidental contact of the product with the skin, rinse with fresh water. Seek medical attention if irritation persists, showing the package leaflet or label to the medical practitioner.
Inhalation:	Not expected to be a hazard.
Ingestion:	In case of ingestion, seek medical advice as a precaution, showing the package leaflet or label to the medical practitioner.
Self-injection:	Care should be taken to avoid accidental self-injection. In case of self-injection, seek medical advice as a precaution, showing the package leaflet or label to the medical practitioner.
4.2 Most important sym	ptoms and effects, both acute and delayed
See Section 11	

SECTION 5: FIRE FIGHTING MEASURES		
5.1 Extinguishing media		
Suitable:	Select extinguishing media suitable for surrounding area.	
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. Cool containers with water spray. Wear full breathing apparatus and self-contained breathing apparatus.	
Fire / explosion hazard:	Irritating and highly toxic gases may be generated from thermal decomposition or combustion.	

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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:	Absorb solution and place into a suitable disposal container.	
Major Spills:	Control personal contact with the substance, by using protective equipment. Absorb solution and place into a suitable disposal container.	

SECTION 7: HANDLING AND STORAGE		
7.1 Precautions for safe h	andling	
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. Protect from light. Following withdrawal of the first dose, use the product within 28 days.	
Storage incompatibility:	Unknown.	
7.3 Specific end uses		
Not available		

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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:							
Ingredient Material Na		ame	TEEL-1	TEEL-2		TEEL-3	
Potassium bromide	Potassium bromide		9.2 mg/m ³	100 mg/m ³		610 mg/m ³	
Ingredient		Origi	Priginal IDLH Revised		Revised ID	IDLH	
Not Available							
8.2 Exposure con	trols						
Appropriate engineering controls:		Proc	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:		Safe	ety glasses with side	shield	ds / 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:		Wea	Wear appropriate clothing				
Other protection:		No s	No special equipment needed when handling small quantities				
Thermal hazards:		Not	Not applicable				
Respiratory protection:		Not	Not applicable				

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8.3 Environmental exposure controls

See Section 12

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Vitbee®: clear, red, sterile solution for injection

Container: 50 ml type I amber glass vial, fitted with a red type I bung and aluminium

overseal. Secondary packaging: cardboard carton

Physical state: Solution Odour: Not available

Odour Threshold: Not available pH (as supplied): Not available

Melting point / freezing point (degrees C): >300°C Initial boiling point and boiling range: >300°C

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): Moderately 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: 1355.42

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.		

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

SECTION 11: TOXI	COLOGICAL INFORMAT	rion .		
Inhalation:	May cause respiratory tra	act irritation.		
Ingestion:	May cause gastrointestinal irritation with nausea, vomiting and diarrhoea. Ingestion of large amounts may cause convulsions, tremors, muscular contractions or spasticity, diarrhoea or fever.			
Skin contact:	May cause skin irritation	and sensitization.		
Eye contact:	Contact may cause trans	ient eye irritation.		
Chronic:	Not expected to cause any chronic health damage.			
Vitbee®:	Acute toxicity	Irritation		
	Not Available	Not Available		
Cyanocobalamin:	Acute toxicity	Irritation		
	Not Available	Not Available		
	rom manufacturer's SDS. ster of Toxic Effect of che	Unless otherwise specified, data extracted mical Substances		
Skin corrosion/ irri	tation:			
Not Available				
Serious eye damaç	ge/ irritation:			
Not available				
Respiratory or skin sensitization:				
May cause skin sensitization in some people.				
Germ cell mutagen	icity:			
Not available				
Carcinogenicity:				
Not available				

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Reproductive toxicity:		
Not contraindicated in pregnant or lactating animals.		
STOT – single exposure:		
Not available		
STOT-repeated exposure:		
Not available		
Aspiration hazard:		
Not available		

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not Available

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Cyanocobalamin	HIGH	HIGH

12.3 Bioaccumulative potential

Ingredient	Bioaccumulative potential		
Cyanocobalamin	LOW (LogKOW = -12.1962)		

12.4 Mobility in Soil

Ingredient	Mobility		
Cyanocobalamin	LOW (KOC = 1000000000)		

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 / Any unused veterinary medicinal product or waste material derived from packaging such veterinary medicinal products should be disposed of in accordance

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disposal:	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	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	Classification code	N/a			
	Hazard Label N/a				
Special provisions N/a					
	Limited quantity	N/a			

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14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a			
Air transport (ICAO-	ATA / DGR):			
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			
14.6 Special	Special provisions	N/a		
precautions for user	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			

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14.3 Transport hazard class(es)	IMDG Class	N/a		
	IMDG Sub risk	-		
14.4 Packing group				
14.5 Environmental hazards				
14.6 Special precautions for user	EMS Number	N/a		
	Special provisions	N/a		
	Limited quantities	antities 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				

SECTION 15: REGULATORY INFORMATION

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

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CYANOCOABALMIN (7758-02-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Customs Inventory of Chemical Substances ECICS (English)
- European Union European Inventory of Existing Commercial Chemical Substabces (EINECS) (English)
- International Agency for research on cancer (IARC) Classified by the IARC Monographs-Agents

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
Cyanocobalamin	7758-02-3	Not Available	01-2120088037-53- XXXX

Harmonization (C&L Inventory)		Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not classified	Not classified	Not classified
2	Skin Irrit. 2, Eye Irrit. 2	GHS07, Wng	H315, H319

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

Australia - AICS	Υ
Canada - DSL	Υ
Canada - NDSL	N (cyanocobalamine)
China - IECSC	Υ
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y (cyanocobalamine)
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)

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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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