SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Clindabactin Chewable Tablets for Dogs and Cats *(available as 55mg, 220mg, 440mg)*
Synonyms:	None
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:	Antibiotic
Uses advised against:	**Not for human use.**
1.3 Details of the supplier of the substance or mixture	
Registered company name (UK):	Le Vet Beheer B.V.
Address:	Wilgenweg 7 3421 TV Oudewater The Netherlands
Telephone:	+31 (0)348 565858
Fax:	+31 (0)348 565454
Website:	www.dechra.com
Email:	Not available
Website:	www.dechra.com
Email:	Not available
1.4 Emergency Telephone Numbers	
	+31 (0)348 565858

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture **This product is exempted from Regulation according to article 1(5) of Reg. (EC) No 1272/2008 and their amendments, because it is a veterinary medicinal products as defined in Directive 2001/82/EC, which is in the finished state, intended for the final user.** **Not classified as Dangerous Goods for transport purposes (EU).**	
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)[1]:	Not applicable
2.2 Label Elements	
Hazard Pictogram:	
Signal Word:	WARNING
Hazard statement(s):	
	H315 Causes skin irritation H319 Causes eye irritation
Supplementary Statement(s) EU:	
	Not applicable
Precautionary Statement(s) Prevention:	
	Not applicable
Precautionary Statement(s) Response:	
	P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P337+P313 If eye irritation persists: Get medical advice/ attention
Precautionary Statement(s) Storage:	
	P405 Store locked up P403+P233 Store in a well ventilated place. Keep container tightly closed
Precautionary Statement(s) Disposal:	
	P501 Dispose of contents/ container in accordance with local regulations

2.3 Other Hazard Information
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.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1.9004-34-6 2.232-674-9 3.Not Available 4.Not Available	30-60	cellulose	Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation); H335 [1]
1.21462-39-5 2.244-398-6 3.Not Available 4.01-2120077696-40-XXXX	30-60	Clindamycin hydrochloride	Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Skin Corrosion/Irritation Category 2, Eye Irritation Category 2; H335, H315, H319 [1]
1.557-04-0 2.209-150-3 3.Not Available 4.Not Available	<1	Magnesium stearate	Eye Irritation Category 2, Skin Corrosion/Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation); H319, H315, H335 [1]
Not available	Not specified	Ingredients determined not be hazardous	Not applicable
Legend:	*1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available*		

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	If accidental eye contamination occurs, flush gently with fresh running water for 15 minutes. Medical advice should be sought if irritation persists.
Skin contact:	In the event of accidental skin contamination, contaminated clothing should be removed and the area washed with large amounts of soap and water. Medical advice should be sought if irritation persists.

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, remove the patient from the contaminated area. Seek medical advice if irritation persists and show the package leaflet or the label to the medical practitioner.
Ingestion:	If swallowed, do not induce vomiting and immediately give water. If discomfort persists, seek medical advice and show the package leaflet or the label to medical practitioner.
4.2 Most important symptoms and effects, both acute and delayed	
Eye contact:	May cause eye irritation.
Skin contact:	May cause skin irritation.
Ingestion:	May cause discomfort if ingested in large quantities
See Section 11 for more detailed information	

4.3 Indication of immediate medical attention and special treatment needed
Treat symptomatically

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:	Use water delivered as a fine spray to control fire and cool adjacent area. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.
Fire / explosion hazard:	Non-combustible.

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. 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.. 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:	When handling, **DO NOT** eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Other Information:	Keep the vial in the outer carton in order to protect from light. This veterinary medicinal product does not require any special temperature storage conditions. Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Aluminium - Polyamide/Aluminium/PVC blister Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or 25 blisters of 10 tablets. Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 tablets.
Storage incompatibility:	Avoid contamination of water or food stuffs.
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

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not available	Not available	Not available	Not available	Not available	Not available	Not available

EMERGENCY LIMITS (EU):

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Not Available	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
Not Available	Not Available	Not Available

8.2 Exposure controls

Appropriate engineering controls:	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.
Personal protection:	
Eye and face protection:	Safety glasses with side shields / chemical goggles
Skin protection:	See hand protection below

Hands/ feet protection:	Wear chemical protective gloves
Body protection:	Wear appropriate clothing
Other protection:	Wear appropriate clothing
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: Chewable Tablet
Container: Aluminium - Polyamide/Aluminium/PVC blister
Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or 25 blisters of 10 tablets.
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 tablets.
Physical state: Solid
Odour: Not available
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not applicable
Flash Point: Not applicable
Evaporation rate Not applicable
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not applicable
Specific Gravity: Not available
Solubility in water and solvents (mg/l): 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
Taste: Not applicable
Surface tension: Not available
Volatile component: Not available
Gas group: Not applicable
pH: Not available
VOC g/L: Not applicable

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 otherwise. Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions:	The product is not considered to be hazardous if used as per instructions.
10.4 Conditions to avoid:	Protect from light.
10.5 Incompatible materials:	See section 7.
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION	
Inhalation:	Due to the nature of the product, the material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation.
Ingestion:	Accidental ingestion of large quantities may cause discomfort.
Skin contact:	May cause inflammation of the skin and may accentuate any pre-existing dermatitis condition. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye contact:	May cause eye irritation in some persons.
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.

Clindabactin Chewable Tablet for Dogs and Cats	**Toxicity**	**Irritation**
	Not available	May cause skin or eye irritation
Cellulose	**Toxicity**	**Irritation**
	Dermal (rabbit) LD50: >2000 mg/kg[2] Inhalation (rat) LC50: >5.8 mg/kg[2] Oral (rat) LD50: >5000 mg/kg[2]	Not available
Clindamycin hydrochloride	**Toxicity**	**Irritation**
	Oral (rat) LD50: 2193 mg/kg[2]	Not available
Magnesium stearate	**Toxicity**	**Irritation**
	Oral (rat) LD50: >10000 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:		
May cause skin corrosion/ irritation.		
Serious eye damage/irritation:		
May cause eye damage/ irritation		
Respiratory or skin sensitization:		
Due to nature of product, not expected to cause respiratory sensitization. Not expected to cause skin sensitization.		
Germ cell mutagenicity:		
Not available		
Carcinogenicity:		
Not available.		
Reproductive toxicity:		
Not available		
STOT – single exposure:		
Not available		
STOT–repeated exposure:		
Not available		

Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

	Endpoint	Test duration (hr)	Species	Value	Source
Clindabactin Chewable Tablets for Dogs and Cats	Not available	Not available	Not available	Not available	Not available
Clindamycin hydrochloride	Not available	Not available	Not available	Not available	Not available
cellulose	LC50 EC50	96 96	Fish Algae or other aquatic plants	9160000 mg/l 340000000 mg/l	3 3
Magnesium stearate	Not available	Not available	Not available	Not available	Not available

Legend: *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
celllulose	LOW	LOW

12.3 Bioaccumulative potential

Ingredient	Bioaccumulative Potential
cellulose	LOW (LogKOW = -5.1249)

12.4 Mobility in Soil

Ingredient	Mobility
cellulose	LOW (KOC = 10)

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. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority. Disposal of this product is controlled by the Misuse of Drugs 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 (EU: ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	
Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	
Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS	

SECTION 15: REGULATORY INFORMATION

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

Cellulose
Europe EC Inventory / EINECS

Clindamycin hydrochloride
Europe EC Inventory / EINECS

Magnesium stearate
Europe EC Inventory / EINECS

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.

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	**CAS number**	**Index Number**	**ECHA Dossier**
Clindamycin hydrochloride	21462-39-5	Not available	01-2120077696-40-XXXX

Harmonization (C&L Inventory)	**Hazard Class and Category Code(s)**	**Pictograms Signal Word Code(s)**	**Hazard Statement Code(s)**
1	Skin sens. 1; Eye irrit. 2	GHS07; Wng	H317; H319
Harmonisation Code 1 = the most prevalent classification. Harmonisation Code 2 = The most severe classification			

National Inventory	**Status**
Australia – AICS	No (clindamycin hydrochloride)
Canada – DSL	No
Canada – NDSL	No (clindamycin hydrochloride, magnesuym stearate)
China – IECSC	No (clindamycin hydrochloride)
Europe - EINEC / ELINCS / NLP	No
Japan – ENCS	No (cellulose)
Korea – KECI	No (clindamycin hydrochloride)
New Zealand – NZIoC	Yes
Philippines – PICCS	Yes
USA – TSCA	No (clindamycin hydrochloride)
Taiwan – TCSI	Yes
Mexico – INSQ	No (clindamycin hydrochloride)
Vietnam – NCI	Yes
Russia – ARIPS	No (clindamycin hydrochloride)
Legend:	*Yes = All ingredients are on the inventory* *No = 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 and ECHA.

Other Information

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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