SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Dexacortone 0.2mg chewable tablets for dogs and cats Dexacortone 0.5mg chewable tablets for dogs and cats
Synonyms:	None
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:	For the symptomatic treatment or as adjunct treatment of inflammatory and allergic conditions in dogs and cats.
Uses advised against:	Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name (EU):	Le Vet Beheer B.V.
Address:	Wilgenweg 7 3421 TV Oudewater The Netherlands
Telephone:	+31 (0)348 565858
Fax:	+31 (0)348 565454
Email:	Not available
1.4 Emergency Telephone Numbers	
	+31 (0)348 565858

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)[1]:	None
2.2 Label Elements	
Signal Word:	Not applicable
Hazard statement(s):	
H315 **H317**	Causes skin irritation May cause an allergic skin reaction

Precautionary Statement(s) Prevention: Not applicable	
Precautionary Statement(s) Response: Not applicable	
Precautionary Statement(s) Storage: Not applicable	
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/container in accordance with local regulations.
2.3 Other Hazard Information May produce an allergic reaction. Possible skin sensitiser	

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)**
1.10039-26-6 2.200-559-2 3.Not Available 4.Not Available	<50	Lactose monohdyrate	Not applicable
1.8013-01-2 2.232-387-9 3.Not Available 4.01-2119539417-34-XXXX	10-30	Yeast extract	Not applicable
1.9003-39-8 2.Not Available 3.Not Available 4.Not Available	1-10	Povidone K30	Not applicable
1.557-04-0 2.209-150-3 3.Not Available 4.Not Available	1-10	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]

1.50-02-2 2.200-003-9 3.Not Available 4.01-2120746369-43-XXXX	<1	Dexamethasone	Skin Sensitizer Category 1; H317 [1]
1.41484-91-7 2.204-823-8 3.Not Available 4.01-2119485123-42-XXXX	<1	Sodium acetate monohydrate	Eye Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Skin Corrosion/Irritation Category 2; H319, H335, H315 [1]
Not available	Proprietary	Other ingredients determined not to 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:	Not expected to be an eye irritant. 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:	Dexamethasone may cause hypersensitivity (allergic) reactions. Skin contact with the product should be avoided, especially in people with known hypersensitivity to dexamethasone or any of the excipients (e.g. povidone or lactose). Wash hands after use. Seek medical advice in case of hypersensitivity reactions.
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:	This product may be harmful to children after accidental ingestion. Do not leave the product unattended. Return unused part-tablets to the blister pack and use them on the next administration. Keep the blister in the outer carton to prevent access by children. In case of accidental ingestion seek medical advice immediately and show the package leaflet or label to the physician.

4.2 Most important symptoms and effects, both acute and delayed
Dexamethasone can cause harm to unborn children. Pregnant women should avoid exposure. Absorption through the skin is negligible but it is recommended to immediately wash hands after handling the tablets to avoid hand-to-mouth contact
4.3 Indication of immediate medical attention and special treatment needed The adverse effects of corticosteroids are almost always due to their use in excess of physiological requirements. Symptomatic treatment is required. Where possible the dose should be withdrawn or reduced. Acute renal insufficiency should be treated with intravenous hydrocortisone sodium succinate with infusions of 0.9% dextrose.

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.

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:	When handling, **DO NOT** eat, drink or smoke. Immediately wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Other Information:	Do not store above 30ºC. Store in the original package in order to protect from light. Keep out of the reach and sight of children.

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	Aluminium - PVC/PE/PVDC blister. Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10 blisters of 10 tablets. Not all pack sizes may be marketed.
Storage incompatibility:	In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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)
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:	No special equipment needed when handling small quantities
Eye and face protection:	No special equipment needed when handling small quantities
Skin protection:	See hand protection below
Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
Body protection:	No special equipment needed when handling small quantities
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: Light brown with brown spots, round and convex flavoured 13 mm tablet with a cross-shaped break line on one side.
Container: Aluminium - PVC/PE/PVDC blister. Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10 blisters of 10 tablets.
Physical state: Chewable tablets
Odour: Not available
Odour Threshold: Not available
pH (as supplied):
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
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): Soluble in water
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:	See Section 7.

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

SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation:	Inhalation of the product is highly unlikely due to how it is packaged and administered. The material is not thought to produce respiratory irritation.	
Ingestion:	This product may be harmful to children after accidental ingestion. Corticosteroids (glucocorticoids) affect carbohydrate, protein and fat metabolism, the cardiovascular system, kidney, skeletal muscle, the nervous system and other organs and tissues. Hypersensitivity reactions may result.	
Skin contact:	Dexamethasone may cause hypersensitivity (allergic) reactions. Skin contact with the product should be avoided, especially in people with known hypersensitivity to dexamethasone or any of the excipients (e.g. povidone or lactose).	
Eye contact:	Not expected to cause eye irritation.	
Chronic:	Dexamethasone can cause harm to unborn children. Pregnant women should avoid exposure.	
Dexamethasone:	**Acute toxicity**	**Irritation**
	Oral (rat) LD_{50}: 14 mg/kg[2]	Not available
Lactose monohydrate:	**Acute toxicity**	**Irritation**
	Oral (rat) LD_{50}: >10000 mg/kg[2]	Not available
Starch:	**Acute toxicity**	**Irritation**
	Not available	Skin (human); 0.3mg/ 3d-I mild
Yeast extract:	**Acute toxicity**	**Irritation**
	Dermal (rat) LD50: >2000 mg/kg[1] Oral (mouse) LD50: >2000 mg/kg[1]	Not available
Povidone:	**Acute toxicity**	**Irritation**
	Oral (rabbit) LD50: 1040 mg/kg^2	Non-irritating

SECTION 11: TOXICOLOGICAL INFORMATION		
Magnesium stearate:	**Acute toxicity**	**Irritation**
	Oral (rat) LD_{50}: >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 irritation		
Serious eye damage/ irritation:		
Not expected to cause eye irritation.		
Respiratory or skin sensitization:		
Not expected to cause respiratory sensitisation. May cause hypersensitivity.		
Germ cell mutagenicity:		
Not available		
Carcinogenicity:		
Not available		
Reproductive toxicity:		
Dexamethasone can cause harm to unborn children. Pregnant women should avoid exposure.		
STOT – single exposure:		
Not available		
STOT–repeated exposure:		
Not available		
Aspiration hazard:		
Not available		

SECTION 12: ECOLOGICAL INFORMATION					
12.1 Toxicity					
Ingredient	**Endpoint**	**Test duration (hr)**	**Species**	**Value**	**Source**
Dexamethasone	EC50	168	Crustacea	0.042-0.076 mg/l	1

Other ingredients	Not available	Not available	Not available	Not available	Not available
			Legend:	*1. 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**
Lactose monohydrate	LOW	LOW
Povidone	LOW	LOW
Dexamethasone	HIGH	HIGH

12.3 Bioaccumulative potential

Ingredient	**Bioaccumulative Potential**
Lactose monohydrate	LOW (LogKOW = -5.1249)
Povidone	LOW (LogKOW = 0.2484)
Dexamethasone	LOW (LogKOW = 1.7207)

12.4 Mobility in Soil

Ingredient	**Mobility**
Lactose monohydrate	LOW (KOC = 10)
Povidone	LOW (KOC = 40.46)
Dexamethasone	LOW (KOC = 95.97)

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 / 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:

Marine pollutant:	NO
Hazchem:	Not Applicable

Land transport (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

THE INGREDIENTS BELOW ARE FOUND ON THE FOLLOWING REGULATORY LISTS:

Lactose monohydrate
Europe EC Inventory/ EINECS

Starch
Europe EC Inventory/ EINECS

Yeast extract
Europe EC Inventory/ EINECS

Povidone
IARC

Magensium stearate
Europe EC Inventory/ EINECS

Dexamethasone
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**
Lactose monohydrate	10039-26-6	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	Not available	Not available
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	**CAS number**	**Index Number**	**ECHA Dossier**
Starch	9005-25-8	Not available	Not available

Harmonization (C&L Inventory)	**Hazard Class and Category Code(s)**	**Pictograms Signal Word Code(s)**	**Hazard Statement Code(s)**
2	Acute Tox. 4; Resp. STOT SE 3; Aquatic Chronic 2; Eye Irrit. 2	GHS07, Wng; GHS09	H332; H335; H411; H319
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	**CAS number**	**Index Number**	**ECHA Dossier**
Yeast extract	8013-01-2	Not available	01-2119539417-34-XXXX

Harmonization (C&L Inventory)	**Hazard Class and Category Code(s)**	**Pictograms Signal Word Code(s)**	**Hazard Statement Code(s)**
2	Flam. Liq. 2	GHS02, Dgr	H225
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	CAS number	Index Number	ECHA Dossier
Povidone	9003-39-8	Not available	Not available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
2	Acute Tox. 4; Acute Tox. 1; Skin Irrit. 2; Eye Irrit. 2; Repr. 1B; Narc. STOT SE 3; STOT RE 2	GHS07; Dgr; Wng	H302; H310 (Cat 1); H315; H319; H335; H360 (Cat 1B); H336; H373
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	CAS number	Index Number	ECHA Dossier
Magnesium stearate	557-04-0	Not available	Not available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
2	Aquatic Chronic 4; Skin Irrit. 2; Eye Irrit. 2; Resp. STOT SE 3; STOT RE 1; Pyr. Sol. 1	GHS07; Wng; GHS08; Dgr; GHS02	H413; H315; H319; H335; H372; H250
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	CAS number	Index Number	ECHA Dossier
Dexamethasone	50-02-2	Not available	01-2120746369-43-XXXX

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
2	Repr. 1B; Skin Irrit. 2; Skin Sens. 1; Eye Irrit. 2; Resp. Sens. 1; Resp. STOT SE 3; Aquatic Chronic 1; Lact.; Acute Tox. 4; Acute Tox. 4; Acute Tox. 4; Carc. 2; STOT RE 1	GHS08; Wng; Dgr; GHS07; GHS09; GHS06	H315; H317 (Cat 1); H319; H334 (Cat 1); H335; H410; H362; H302; H312; H332; H351; H372; H360 (Cat 1B)
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

National Inventory	Status
Australia – AICS	Y
Canada – DSL	N (dexamethasone)
Canada – NDSL	N (lactose monohydrate, yeast extract, Povidone, magnesium stearate)
China – IECSC	N (dexamethasone)
Europe - EINEC / ELINCS / NLP	N (Povidone)
Japan – ENCS	N (yeast extract)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
Taiwan – TCSI	Y
Mexico – INSQ	Y
Vietnam – NCI	Y
Russia -ARIPS	N (yeast extract, dexamethasone)
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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