



SECTION 1: IDENTIFICATION

1.1 Product identifier

Product name:	Spizobactin 750,000 IU / 125 mg Chewable Tablets for Dogs
Synonyms:	None
Proper Shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains spiramycin)
Other means of identification:	None

1.2 Relevant identified uses of the substances or mixture and uses advised against

Recommended uses:	Antibacterials for systemic use – Spiramycin and metronidazole
Uses advised against:	Not for human use

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

1.4 Emergency Telephone Numbers

	+44 (0) 1756 791311
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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹:	H315 - Skin Corrosion/Irritation Category 2, H317 - Sensitisation (Skin) Category 1, H318 - Serious Eye Damage/Eye Irritation Category 1, H334 - Sensitisation (Respiratory) Category 1, H335 - Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, H350 - Carcinogenicity Category 1B, H373 - Specific Target Organ Toxicity - Repeated Exposure Category 2, H411 - Hazardous to the Aquatic Environment Long-Term Hazard Category 2
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1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

2.2 Label Elements	
Hazard Pictogram:	
Signal Word:	Danger
Hazard statement(s):	
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H350	May cause cancer.
H373	May cause damage to organs through prolonged or repeated exposure.
H411	Toxic to aquatic life with long lasting effects.
Supplementary Statement(s): Not applicable	
Precautionary Statement(s) Prevention:	
P201	Obtain special instructions before use.
P260	Do not breathe dust/fume.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P284	[In case of inadequate ventilation] wear respiratory protection.
P273	Avoid release to the environment.
P264	Wash all exposed external body areas thoroughly after handling.
P201	Obtain special instructions before use.
Precautionary Statement(s) Response:	
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/ attention.
P310	Immediately call a POISON CENTER/doctor/physician/first aider.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician/first aider.
P302+P352	IF ON SKIN: Wash with plenty of water.

P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.
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 to authorised hazardous or special waste collection point in accordance with any local regulation.
2.3 Other Hazard Information Inhalation and/or ingestion may produce health damage*. May possibly affect fertility*. REACH - Art.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 'Composition of mixtures' in Section 3.2			
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)
1.8025-81-8 2.232-429-6 3.Not Available 4.Not Available	10-30	<u>spiramycin</u>	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Sensitisation (Skin) Category 1, Sensitisation (Respiratory) Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 2; H315, H319, H317, H334, H335, H411 ^[1]
1.443-48-1 2.207-136-1 3.Not Available 4.01-2120759512-53-XXXX	10-30	<u>metronidazole</u>	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 1, Carcinogenicity Category 1B, Specific Target Organ Toxicity - Repeated Exposure Category 2; H315, H318, H350, H373 ^[1]
1.9057-07-2 2.232-679-6 232-686-4 3.Not Available	10-30	<u>starch</u>	Not Applicable

4. Not Available			
1. 68602-94-8 2. 283-294-5 3. Not Available 4. 01-2119539417-34-XXXX	10-30	<u>yeast, dried</u>	Not Applicable
1. 9004-34-6 2. 232-674-9 3. Not Available 4. Not Available	1-10	<u>cellulose, microcrystalline</u>	Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H335 ^[1]
1. 71187-19-4 2. Not Available 3. Not Available 4. Not Available	1-10	<u>silica, colloidal</u>	Not Applicable
1. 557-04-0 2. 209-150-3 3. Not Available 4. Not Available	1-10	<u>magnesium stearate</u>	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H315, H319, H335 ^[1]
Not Available	balance	Ingredients determined not to be hazardous	Not Applicable
1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties			

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	Accidental spillage on the eyes should be washed off immediately with plenty of water. Remove contact lenses if possible. Seek medical advice if pain and irritation persists and show the package leaflet or the label to the medical practitioner.
Skin contact:	In the case of contact with skin, wash with soap and water. If irritation persists, seek medical advice. Wash hands after use.
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. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration and immediately give water. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. 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 See Section 11	
4.3 Indication of immediate medical attention and special treatment needed Treat symptomatically.	

SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media Water spray or fog, foam, dry chemical powder, BCF (where regulations permit), carbon dioxide	
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.
5.3 Special protective actions for fire-fighters:	
Firefighting:	Use water delivered as a fine spray to control fire and cool adjacent area. Do not approach containers suspected to be hot. 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:	Solid which exhibits difficult combustion or is difficult to ignite On combustion, may emit toxic fumes of carbon monoxide.

SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures 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	Wear suitable protection gloves and clothing when handling the product. Avoid all personal contact, including inhalation. When handling, DO NOT eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Fire and explosion protection	See section 5
Other Information	Store in original containers. Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Keep out of the reach and sight of children. Observe manufacturer's storage and handling recommendations contained within this SDS. For major quantities: Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams).. Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container	Aluminium - PVC/PE/PVDC blister.
Storage incompatibility	Avoid contamination of water, foodstuffs or feed. Avoid reaction with oxidising agents

7.3 Specific end uses

See section 1

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Ingredient	SNELs Exposure Pattern Worker	PNECs Compartment
yeast, dried	Dermal 12.5 mg/kg bw/day (Systemic, Chronic) Inhalation 22.1 mg/m ³ (Systemic, Chronic) Dermal 7.5 mg/kg bw/day (Systemic, Chronic) * Inhalation 6.52 mg/m ³ (Systemic, Chronic) * Oral 7.5 mg/kg bw/day (Systemic, Chronic) *	Not Available

* Values for General Population

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
UK Workplace Exposure Limits	starch	Starch: total inhalable	10 mg/m ³	Not Available	Not Available	Not Available

(WELs)	starch	Starch: respirable	4 mg/m ³	Not Available	Not Available	Not Available
	Cellulose, microcrystalline	Cellulose: inhalable dust	10 mg/m ³	20 mg/m ³	Not Available	Not Available
	Cellulose, microcrystalline	Cellulose: respirable	4 mg/m ³	Not Available	Not Available	Not Available
EMERGENCY LIMITS:						
Ingredient		TEEL-1	TEEL-2	TEEL-3		
starch		30 mg/m ³	330 mg/m ³	2,000 mg/m ³		
Ingredient	Original IDLH		Revised IDLH			
All ingredients	Not available		Not available			
Occupational Exposure Banding						
Ingredient	Occupational Exposure Band Rating		Occupational Exposure Band Limit			
spiramycin	E		≤ 0.01 mg/m ³			
metronidazole	E		≤ 0.01 mg/m ³			
magnesium stearate	E		≤ 0.01 mg/m ³			
Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.						
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. 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:		When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: Chemical goggles, face shield, full face shield may be required for supplementary but never for primary protection of eyes, contact lenses may pose a special hazard				
Skin protection:		See hand protection below				
Hands/ feet protection:		The material may produce skin sensitisation in predisposed				



	individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. Contaminated leather items, such as shoes, belts and watchbands should be removed and destroyed
Body protection:	Wear appropriate clothing
Other protection:	No special equipment needed when handling small quantities. Employees working with confirmed human carcinogens should be provided with, and be required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), shoe covers and gloves prior to entering the regulated area. Emergency shower and eye wash to be provided.
Thermal hazards:	Not applicable
Respiratory protection:	Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent)
8.3 Environmental exposure controls See Section 12	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
9.1 Information on basic physical and chemical properties
<p>Appearance: Light brown with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side</p> <p>Container: Aluminium - PVC/PE/PVDC blister, Cardboard box of 1, 2 or 3 blisters of 10 tablets</p> <p>Physical state: Solid</p> <p>Odor: Not available</p> <p>Melting point / freezing point (degrees C): Not available</p> <p>Initial boiling point and boiling range: Not applicable</p> <p>Flash Point: Not applicable</p> <p>Evaporation rate Not applicable</p> <p>Flammability: Not available</p> <p>Upper/lower flammability or explosive limits: Not available</p> <p>Vapor pressure: Not applicable</p> <p>Specific Gravity: Not available</p> <p>Solubility in water and solvents (mg/L): Not available</p> <p>Auto ignition temperature (degrees C): Not available</p> <p>Decomposition temperature (degrees C): Not available</p> <p>Viscosity: (degrees C): Not available</p> <p>Explosive properties: Not available</p> <p>Oxidizing properties: Not available</p> <p>Partition Coefficient: Not available</p> <p>Taste: Not available</p> <p>Surface tension: Not available</p> <p>Volatile component: Not available</p> <p>Gas group: Not available</p> <p>pH: 3 Not available</p>

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	Product is considered stable. Unstable in the presence of incompatible materials Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions	See Section 7.
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:	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:	Due to the nature of the product, it is unlikely large quantities will be ingested. However, accidental ingestion of the material may be damaging to the health of the individual..Aromatase inhibitors (including triazoles and azoles) produce several side effects including mood swing, depression, weight gain, hot flushes, vaginal dryness, bloating, early onset of menopause. Long-term use may result in bone weakness, increased risk of blood clots, gastrointestinal disturbance, and sweats.	
Skin contact:	Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis. Open cuts, abraded or irritated skin should not be exposed to this material.	
Eye contact:	When applied to the eye(s) of animals, the material produces severe ocular lesions which are present twenty-four hours or more after instillation.	
Chronic:	Due to the nature of the product, it is likely that humans will be exposed for long periods. Repeated or long-term occupational exposure is likely to produce cumulative health effects involving organs or biochemical systems. Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.	
Spizobactin 750,000 IU/125 mg Chewable Tablets for Dogs	Toxicity	Irritation
	Not available	Not Available
spiramycin	Toxicity	Irritation
	Oral(mouse) LD ₅₀ : >2900 mg/kg ^[2]	Not Available

metronidazole	Toxicity	Irritation
	Oral(rat) LD ₅₀ : 3000 mg/kg ^[1]	Not available
starch	Toxicity	Irritation
	Not available	Skin(human): 0.3 mg/3d-I mild
yeast, dried	Toxicity	Irritation
	Dermal (rat) LD ₅₀ >2000 mg/kg ^[2] Oral (mouse) LD ₅₀ >2000 mg/kg ^[2]	Not available
cellulose, microcrystalline	Toxicity	Irritation
	Dermal (rabbit) LD ₅₀ >2000 mg/kg ^[2] Inhalation (rat) LC ₅₀ :>5.8 mg/kg ^[2] Oral (rat) LD ₅₀ >5000 mg/kg ^[2]	Not available
silica, colloidal	Toxicity	Irritation
	Not available	Not available
magnesium stearate	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

Acute Toxicity	✘	Carcinogenicity	✔
Skin Irritation/Corrosion	✔	Reproductivity	✘
Serios Eye Damage/Irritation	✔	STOT – Single Exposure	✔
Respiratory or Skin Sensitization	✔	STOT – Repeated Exposure	✔
Mutagenicity	✘	Aspiration Hazard	✘

✘ - Data either not available or does not fill the criteria for classification
 ✔ - Data available to make classification

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Spizobactin 750,000 IU/125 mg Chewable Tablets for Dogs	Not available	Not available	Not available	Not available	Not available
spiramycin	EC50(ECx)	168h	Algae or other aquatic plants	0.001-0.018mg/l	4
	EC50	72h	Algae or other aquatic plants	1.3-4mg/l	4

metronidazole	EC50(ECx)	48h	Crustacea	170-258mg/l	4
	LC50	96h	Fish	>142.6mg/L	4
	EC50	48h	Crustacea	170-258mg/l	4
All other ingredients	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

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability			
Ingredient	Persistence: Water/Soil	Persistence: Air	
spiramycin	HIGH	HIGH	
metronidazole	HIGH	HIGH	
cellulose	LOW	LOW	
12.3 Bioaccumulative potential			
Ingredient	Bioaccumulative Potential		
spiramycin	LOW (LogKOW = -1.4081)		
metronidazole	LOW (LogKOW = -0.02)		
cellulose	LOW (LogKOW = -5.1249)		
12.4 Mobility in Soil			
Ingredient	Mobility		
metronidazole	LOW (KOC = 10)		
cellulose	LOW (KOC = 10)		
12.5 Results of PBT and vPvB assessment			
	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT	✘	✘	✘
vPvB	✘	✘	✘
PBT Criteria fulfilled?	No		
vPvB	No		
12.6. Endocrine Disruption Properties			
Not Available			

12.7 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. DO NOT allow wash water from cleaning or process equipment to enter drains.
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available

SECTION 14: TRANSPORT INFORMATION

Labels required		
Marine pollutant:	NO	
Hazchem:	22	
Land transport (ADR)		
14.1 UN Number	3077	
14.2 UN Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains spiramycin)	
14.3 Transport hazard class(es)	Class Subrisk	9 Not Applicable
14.4 Packing group	III	
14.5 Environmental hazards	Environmentally hazardous	
14.6 Special precautions for user	Hazard Identification (Kemler) Classification code Hazard label Special provisions Limited quantity Tunnel Restriction Code	90 M7 9 274 335 375 601 5 kg 3 (-)
Air transport (ICAO-IATA / DGR)		
14.1 UN Number	3077	
14.2 UN Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains spiramycin)	



14.3 Transport hazard class(es)	ICAO/IATA Class ICAO / IATA Subrisk ERG Code	9 Not Applicable 9L
14.4 Packing group	III	
14.5 Environmental hazards	Environmentally hazardous	
14.6 Special precautions for user	Special provisions Cargo Only Packing Instructions Cargo Only Maximum Qty / Pack Passenger and Cargo Packing Instructions Passenger and Cargo Maximum Qty / Pack Passenger and Cargo Limited Quantity Packing Instructions Passenger and Cargo Limited Maximum Qty / Pack	A97 A158 A179 A197 A215 956 400 kg 956 400 kg Y956 30 kg G
Sea transport (IMDG-Code / GGVSee)		
14.1 UN Number	3077	
14.2 UN Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains spiramycin)	
14.3 Transport hazard class(es)	IMDG Class IMDG Subrisk	9 Not Applicable
14.4 Packing group	III	
14.5 Environmental hazards	Marine Pollutant	
14.6 Special precautions for user	EMS Number Special provisions Limited Quantities	F-A , S-F 274 335 966 967 969 5 kg
Inland waterways transport (ADN)		
14.1 UN Number	3077	
14.2 UN Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains spiramycin)	
14.3 Transport hazard class(es)	9	Not Applicable
14.4 Packing group	III	
14.5 Environmental hazards	Environmentally hazardous	
14.6 Special precautions for user	Classification code Special provisions Limited Quantity Equipment required Fire cones number	M7 274; 335; 375; 601 5 kg PP, A*** 0
14.7 Transport in bulk according to Annex II of MARPOL and the IBC code		

Not Applicable
14.8 Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code Not Available for any ingredient
14.9 Transport in bulk in accordance with the ICG Code Not Available for any ingredient

SECTION 15: REGULATORY INFORMATION

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

Spiramycin

Europe EC Inventory / EU - European Inventory of Existing Commercial Chemical Substances (EINECS)

Metronidazole

Chemical Footprint Project - Chemicals of High Concern List / Europe EC Inventory / EINECS / International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs / International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans

Starch

Europe EC Inventory / EINECS

Yeast, dried

Europe EC Inventory / EINECS

Cellulose, microcrystalline

Europe EC Inventory / EINECS / International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

Silica, colloidal

Not Applicable

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 - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

15.2 Chemical Safety Assessment

Product regulated as a veterinary product and is prescribed by veterinarians as antibacterials for systemic use in dogs.

ECHA SUMMARY

Not Applicable

National Inventory	Status
Austrália – AICS / Australia Non-Industrial Use	No (silica, colloidal)

Canada – DSL	No (spiramycin; silica, colloidal)
Canada – NDSL	No (spiramycin; metronidazole; yeast, dried; silica, colloidal; magnesium stearate)
China – IECSC	No (spiramycin)
Europe - EINEC / ELINCS /NLP	No (silica, colloidal)
Japan – ENCS	No (metronidazole; yeast, dried; cellulose; silica, colloidal)
Korea – KECI	No (yeast, dried; silica, colloidal)
New Zealand – NZIoC	No (silica, colloidal)
Philippines – PICCS	No (spiramycin)
USA – TSCA	No (spiramycin; metronidazole; silica, colloidal)
Taiwan – TCSI	Yes
Mexico – INSQ	No (yeast, dried; silica, colloidal)
Vietnam – NCI	No (silica, colloidal)
Russia – FBEPH	No (spiramycin; metronidazole; yeast, dried; silica, colloidal)
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

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. 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. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit.



IDLH: Immediately Dangerous to Life or Health Concentrations
ES: Exposure Standard
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
AIIIC: Australian Inventory of Industrial Chemicals
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
NLP: No-Longer Polymers
ENCS: Existing and New Chemical Substances Inventory
KECI: Korea Existing Chemicals Inventory
NZIoC: New Zealand Inventory of Chemicals
PICCS: Philippine Inventory of Chemicals and Chemical Substances
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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