SAFETY DATA SHEETS

This SDS packet was issued with item:

078936858

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078928778 078937198 078937224 078938015 078944764 078944769 078944797 078945422 078945455 078945456 078945457 078950117 078950401

SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name	Clavacillin® (amoxicillin and clavulanate potassium tablets), USP Veterinary Tablets
Chemical name	Not Applicable
Synonyms	Amoxicillin and clavulanate potassium tablets
Chemical formula	Not Applicable
Other means ofidentification	Not Available
1.2 Recommended use of the chemical and restrictions on use	
Relevant identified uses	Oral tablet / antibiotic. For professional use only. Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name (US)	Dechra Veterinary Products
Address	7015 College Blvd, Suite 525, Overland Park, KS 66211 USA
Telephone	866-933-2472
Fax	Not Available
Email	Not Available
1.4 Emergency telephone numbers	
Dechra (US)	866-933-2472

SECTION 2: HAZARD(S) IDENTIFICATION	
2.1 Classification of the substance or mixture **NFPA 704 diamond**	 Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)
Classification	Skin Corrosion/Irritation Category 2, Sensitization (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2A, Sensitization (Respiratory) Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, Carcinogenicity Category 1A, Specific Target Organ Toxicity - Repeated Exposure Category 2
2.2 Label elements	
Hazard pictogram(s)	
Signal word	**Danger**
Hazard statement(s)	
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
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.
Hazard(s) not otherwise classified Not Applicable	
Precautionary statement(s) Prevention	
P201	Obtain special instructions before use.
P260	Do not breathe dust/fume.
P261	Avoid breathing dust/fumes.
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.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash all exposed external body areas thoroughly after handling.
P272	Contaminated work clothing must not be allowed out of the workplace.
Precautionary statement(s) Response	
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/ attention.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician/first aider.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.
P314	Get medical advice/attention if you feel unwell.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
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.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances
See section below for composition of Mixtures.

3.2 Mixtures

CAS No.	% [weight]	Name
61336-70-7	30-60	amoxycillin trihydrate
9004-34-6	30-60	microcrystalline cellulose
61177-45-5	10-30	potassium clavulanate
9063-38-1	1-10	sodium starch glycolate
557-04-0	1-10	magnesium stearate
9004-65-3	<1	hydroxypropyl methylcellulose
7631-86-9	<1	colloidal silicon dioxide
13463-67-7	<1	titanium dioxide
25322-68-3	<1	polyethylene glycol 6000
14807-96-6	<1	talc
51274-00-1	<1	iron oxide yellow

The exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact	If this product comes in contact with the eyes: wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin contact	If skin contact occurs: immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor, without delay.
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. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice.

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
There is no restriction on the type of extinguisher which may be used. Use extinguishing media appropriate for surrounding fire.

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	Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use firefighting procedures suitable for surrounding 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. Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Explosion may emit poisonous/corrosive fumes. When heated to extreme temperatures, (>1700°C) amorphous silica can fuse.

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	
Minor spills	Clean up waste regularly and abnormal spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. Vacuum up or sweep up. **NOTE:** Vacuum cleaner must be fitted with an exhaust micro filter (H-Class HEPA type) (consider explosion-proof machines designed to be grounded during storage and use). H-Class HEPA filtered industrial vacuum cleaners should **NOT** be used on wet materials or surfaces. Dampen with water to prevent dusting before sweeping. Place in suitable containers for disposal.
Major spills	Moderate hazard. **CAUTION**: Advise personnel in area. Alert Emergency Services and tell them location and nature of hazard. Control personal contact by wearing protective clothing. Prevent, by any means available, spillage from entering drains or water courses. Recover product wherever possible. **IF DRY:** Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. **IF WET:** Vacuum/shovel up and place in labelled containers for disposal. **ALWAYS:** Wash area down with large amounts of water and prevent runoff into drains. If contamination of drains or waterways occurs, advise Emergency Services.
Personal Protective Equipment advice is contained in Section 8 of the SDS.	

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling	
Safe handling	Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. **DO NOT** enter confined spaces until atmosphere has been checked. **DO NOT** allow material to contact humans, exposed food or food utensils. Avoid contact with incompatible materials. When handling, **DO NOT** eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Launder contaminated clothing before re-use. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this SDS.
Other information	Store in original containers. Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks. 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	Tablets are packaged in foil strip packs. Glass container is suitable for laboratory quantities Polyethylene or polypropylene container. Check all containers are clearly labelled and free from leaks.
Storage incompatibility	Protect from direct sunlight. Do not freeze. Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (between 59° and 86°F). Avoid strong acids, bases and oxidizing agents.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US OSHA Permissible Exposure Limits (PELs)Table Z-3	microcrystalline cellulose	Inert or Nuisance Dust: Respirable fraction	5 mg/m^3 / 15mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3		Inert or Nuisance Dust: Total Dust	15 mg/m^3 / 50mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1		Cellulose- Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1		Cellulose- Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)		Cellulose - total	10 mg/m^3	Not Available	Not Available	Not Available
US NIOSH RELs		Cellulose - respirable	5 mg/m^3	Not Available	Not Available	Not Available
US ACGIH Threshold Limit Values (TLV)		Cellulose	10 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3	magnesium stearate	Inert or Nuisance Dust: Respirable fraction	5 mg/m^3 / 15mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3		Inert or Nuisance Dust: Total Dust	15 mg/m^3 / 50mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1		Particulates Not Otherwise Regulated(PNOR)- Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1		PNOR - Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available

US NIOSH (RELs		PNOR	Not Available	Not Available	Not Available	See Appendix D
US ACGIH TLV		Stearates (Inhalable particulate matter)	10 mg/m^3	Not Available	Not Available	A4
US ACGIH TLV		Stearates (Respirable particulatematter)	3 mg/m^3	Not Available	Not Available	A4
US OSHA PELs Table Z-3	colloidal silicon dioxide	Amorphous, including natural diatomaceous earth	80 (%SiO_2) mg/m^3 / 20 mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1		PNOR - Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1		PNOR - Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US NIOSH RELs		Silica, amorphous	6 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3	titanium dioxide	Inert or Nuisance Dust: Total Dust	15 mg/m^3 / 50 mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3		Inert or Nuisance Dust: Respirablefraction	5 mg/m^3 / 15 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs)Table Z-1		Titanium dioxide - Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US NIOSH RELs		Titanium dioxide	Not Available	Not Available	Not Available	Ca; See Appendix A
US ACGIH TLV		Titanium dioxide	10 mg/m^3	Not Available	Not Available	(A4)
US OSHA PELs Table Z-3	talc	Silicates (less than 1% crystallinesilica): Soapstone	20 mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3		Silicates (less than 1% crystallinesilica): Talc (containing asbestos)	Not Available	Not Available	Not Available	Use asbestos limit
US OSHA PELs Table Z-3		Silicates (less than 1% crystalline silica): Talc (not containing asbestos)	20 mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1		PNOR - Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1		PNOR - Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US NIOSH RELs		Talc (containing no asbestos and lessthan 1% quartz) - respirable	2 mg/m^3	Not Available	Not Available	Not Available
US ACGIH Threshold Limit Values (TLV)		Talc: Containing asbestos fibers	Not Available	Not Available	Not Available	A1
US ACGIH TLV		Talc: Containing no asbestos fibers(Respirable particulate matter)	2 mg/m3	Not Available	Not Available	A4
US OSHA PELs Table Z-3	iron oxide yellow	Inert or Nuisance Dust: Respirablefraction	5 mg/m^3 / 15 mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-3		Inert or Nuisance Dust: Total Dust	15 mg/m^3 / 50 mppcf	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1		PNOR - Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US OSHA PELs Table Z-1		PNOR - Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available
US NIOSH RELs		PNOR	Not Available	Not Available	Not Available	See Appendix D

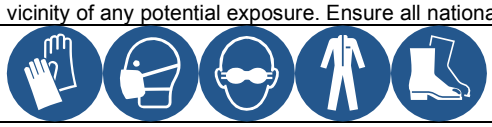
Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
colloidal silicon dioxide	18 mg/m^3	200 mg/m^3	1,200 mg/m^3
	18 mg/m^3	100 mg/m^3	630 mg/m^3
	120 mg/m^3	1,300 mg/m^3	7,900 mg/m^3
	45 mg/m^3	500 mg/m^3	3,000 mg/m^3
	18 mg/m^3	740 mg/m^3	4,500 mg/m^3
titanium dioxide	30 mg/m^3	330 mg/m^3	2,000 mg/m^3
polyethylene glycol 6000	30 mg/m^3	1,300 mg/m^3	7,700 mg/m^3

Ingredient	Original IDLH	Revised IDLH
amoxicillin trihydrate	Not Available	Not Available
microcrystalline cellulose	Not Available	Not Available
potassium clavulanate	Not Available	Not Available
sodium starch glycolate	Not Available	Not Available
magnesium stearate	Not Available	Not Available
hypromellose E5	Not Available	Not Available

colloidal silicon dioxide	3,000 mg/m3	Not Available
titanium dioxide	5,000 mg/m3	Not Available
polyethylene glycol 6000	Not Available	Not Available
talc	1,000 mg/m^3	Not Available
iron oxide yellow	Not Available	Not Available
Occupational Exposure Banding		
Ingredient	**Occupational Exposure Band Rating**	**Occupational Exposure Band Limit**
amoxicillin trihydrate	E	≤ 0.01 mg/m³
potassium clavulanate	E	≤ 0.01 mg/m³
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 exposureband (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health		

8.2 Exposure controls

Appropriate engineering controls	Avoid creating or spreading dust. Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.
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 wear chemical goggles with side-shields. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use,
Skin and body protection	Wear suitable protective clothing if skin contact with drug product is possible. See Hand protection above.
Hand/feet protection	The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and otherprotective equipment, to avoid all possible skin contact. Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).
Other protection	For up to 500 g a laboratory coat may be suitable. For up to 1 kg a disposable laboratory coat or coverall of low permeability is recommended. Coveralls shouldbe buttoned at collar and cuffs. For over 1 kg and manufacturing operations, wear disposable coverall of low permeability and disposableshoe covers. Eye wash unit and ready access to an emergency shower. For Emergencies: Vinyl suit
Respiratory protection	Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent). If exposure limits are exceeded or irritation is experienced, ventilation and excavation may be required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Yellowish tablets Physical state: Solid Odor: Not Available Odor threshold: Not Available pH (as supplied): Not Available Melting point / freezing point (°C): Not Available Initial boiling point and boiling range: Not Available Flash point (°C): Not Available Evaporation rate: Not Available Flammability: Not Available Upper/lower flammability or explosive limits: Not Available Vapor pressure: Not Available Relative density (Water = 1): Not Available Solubility in water (mg/l): Immiscible	Vapor density: Not Available Auto ignition temperature (°C): Not Available Decomposition temperature (°C): Not Available Viscosity (°C): Not Available Explosive properties: Not Available Oxidizing properties: Not Available Partition coefficient: Not Available Molecular weight: Not Available Taste: Not Available Surface tension: Not Available Volatile component (%vol): Not Available Gas group: Not Available pH as a solution: Not Available VOC g/L: Not Available Specific gravity @ 20°C (water = 1): Not Available

SECTION 10: STABILITY AND REACTIVITY

Reactivity	See Section 7
Chemical stability	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.
Possibility of hazardous reactions	See Section 7
Conditions to avoid	See Section 7
Incompatible materials	See Section 7
Hazardous composition	See Section 5

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Inhaled	Inhalation of vapors or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual.	
Ingestion	Accidental ingestion of the material may be damaging to individual's health.	
Skin contact	The liquid may be miscible with fats or oils and may degrease the skin, producing a skin reaction described as non-allergic contact dermatitis. The material is unlikely to produce an irritant dermatitis as described in EC Directives Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects.	
Eye	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.	
Chronic	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions.	
Clavacillin (amoxicillin and clavulanate potassium tablets) USP Veterinary Tablets	**Toxicity**	**Irritation**
	Not Available	Not Available
amoxycillin trihydrate	**Toxicity**	**Irritation**
	Dermal(rat) LD_{50} >2000 mg/kg[1] Oral(rat) LD_{50} >2000 mg/kg[1]	Not Available
microcrystalline cellulose	**Toxicity**	**Irritation**
	Dermal(rabbit) LD_{50} >2000 mg/kg[2] Inhalation(rat) LC_{50} >5.8 mg/L4h[2] Oral(rat) LD_{50} >5000 mg/kg[2]	Not Available
potassium clavulanate	**Toxicity**	**Irritation**
	Oral(mouse) LD_{50}: 4526 mg/kg[2]	Not Available
magnesium stearate	**Toxicity**	**Irritation**
	Oral(rat) LD_{50} >10000 mg/kg[2]	Not Available
hypromellose E5	**Toxicity**	**Irritation**
	Oral(rat) LD_{50} >10000 mg/kg[2]	Not Available
colloidal silicon dioxide	**Toxicity**	**Irritation**
	Dermal(rat) LD_{50} >2000 mg/kg[1] Inhalation(rat) LC_{50} >0.139 mg/L4h[1] Oral(rat) LD_{50} >1000 mg/kg[1]	Eye(rabbit): non-irritating* Eye: no adverse effect observed (not irritating)[1] Skin(rabbit): non-irritating* Skin: no adverse effect observed (not irritating)[1]
titanium dioxide	**Toxicity**	**Irritation**
	Dermal (hamster) LD_{50} >=10000 mg/kg[2] Inhalation(rat) LC_{50} >2.28 mg/l4h[1] Oral(rat) LD_{50} >=2000 mg/kg[1]	Eye: no adverse effect observed (not irritating)[1] Skin(human): 0.3 mg /3D (int)-mild* Skin: no adverse effect observed (not irritating)[1]
polyethylene glycol 6000	**Toxicity**	**Irritation**
	Dermal (rat) LD_{50} >2000 mg/kg[1] Oral(rat) LD_{50}; 600 mg/kg[2]	Eye(rabbit): 500 mg/24h –mild Eye: no adverse effect observed (not irritating)[1] Skin(rabbit): 500mg (open) mild. Skin: no adverse effect observed (not irritating)[1]
talc	**Toxicity**	**Irritation**
	Dermal (rat) LD_{50} >2000 mg/kg[1] Inhalation(rat) LC50; >2.1 mg/l4h[1] Oral(rat) LD_{50} >5000 mg/kg[1]	Eye: no adverse effect observed (not irritating)[1] Skin(human): 0.3 mg/3d-I mild Skin: no adverse effect observed (not irritating)[1]
iron oxide yellow	**Toxicity**	**Irritation**
	Oral(rat) LD_{50} >5000 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**	✖
Serious EyeDamage/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: No additional information available

Clavacillin (amoxicillin and clavulanate potassium tablets), USP Veterinary Tablets	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
amoxycillin trihydrate	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	EC50	96h	Algae or other aquatic plants	0.002mg/l	2
	EC50	72h	Algae or other aquatic plants	56.3mg/l	2

	LC50	96h	Fish	>100mg/l	2
	EC50	48h	Crustacea	>1000mg/l	2
	NOEC(ECx)	96h	Algae or other aquatic plants	0.001mg/l	2
microcrystalline cellulose	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
potassium clavulanate	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
sodium starch glycolate	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
magnesium stearate	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
hypromellose E5	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
colloidal silicon dioxide	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	EC0(ECx)	24h	Crustacea	>=10000mg/l	1
	EC50	72h	Algae or other aquatic plants	14.1mg/l	2
	LC50	96h	Fish	1033.016mg/l	2
	EC50	48h	Crustacea	>86mg/l	2
	EC50	96h	Algae or other aquatic plants	217.576mg/l	2
titanium dioxide	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	EC50	72h	Algae or other aquatic plants	3.75-7.58mg/l	4
	BCF	1008h	Fish	<1.1-9.6	7
	EC50	48h	Crustacea	1.9mg/l	2
	LC50	96h	Fish	1.85-3.06mg/l	4
	NOEC(ECx)	504h	Crustacea	0.02mg/l	4
	EC50	96h	Algae or other aquatic plants	179.05mg/l	2
polyethylene glycol 6000	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	EC50	48h	Crustacea	>100mg/l	2
	LC50	96h	Fish	>100mg/l	2
	EC50(ECx)	96h	Algae or other aquatic plants	>100mg/l	2
	EC50	96h	Algae or other aquatic plants	>100mg/l	2
talc	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	LC50	96h	Fish	89581.016mg/l	2
	NOEC(ECx)	720h	Algae or other aquatic plants	918.089mg/l	2
	EC50	96h	Algae or other aquatic plants	7202.7mg/l	2
iron oxide yellow	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	NOEC(ECx)	504h	Fish	0.52mg/l	2
	EC50	72h	Algae or other aquatic plants	18mg/l	2
	LC50	96h	Fish	0.05mg/l	2

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: No additional information available

Ingredient	**Persistence: Water/Soil**	**Persistence: Air**
amoxycillin trihydrate	HIGH	HIGH
microcrystalline cellulose	LOW	LOW
colloidal silicon dioxide	LOW	LOW
titanium dioxide	HIGH	HIGH
polyethylene glycol 6000	LOW	LOW

12.3 Bioaccumulative potential: No additional information available

Ingredient	**Bioaccumulation**
amoxycillin trihydrate	LOW (LogKOW = 0.87)
microcrystalline cellulose	LOW (LogKOW = -5.1249)
colloidal silicon dioxide	LOW (LogKOW = 0.5294)
titanium dioxide	LOW (BCF = 10)
polyethylene glycol 6000	LOW (LogKOW = -1.1996)

12.4 Mobility in soil: No additional information available

Ingredient	**Mobility**
amoxycillin trihydrate	LOW (KOC = 865.5)
microcrystalline cellulose	LOW (KOC = 10)
colloidal silicon dioxide	LOW (KOC = 23.74)
titanium dioxide	LOW (KOC = 23.74)
polyethylene glycol 6000	HIGH (KOC = 1)

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product/packaging disposal	Containers may still present a chemical hazard/danger when empty. Return to supplier for reuse/ recycling if possible. Otherwise: If container cannot be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. Where possible retain label warnings

	and SDS and observe all notices pertaining to the product. **DO NOT** allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal. In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. Where in doubt contact the responsible authority.

SECTION 14: TRANSPORT INFORMATION

Labels required

Marine pollutant	NO

Shipping container and transport vehicle placarding and labeling may vary from the below information. Products that are regulated for transport will be packaged and marked as Dangerous Goods in Excepted Quantities according to US DOT, IATA and IMDG regulations. In case of reshipment, it is the responsibility of the shipper to determine the appropriate labels and markings in accordance with applicable transport regulations.

Land transport (DOT): 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

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
	Not Available for any ingredient

Transport in bulk in accordance with ICG Code

Product name	Group
	Not Available for any ingredient

SECTION 15: REGULATORY INFORMATION

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

Product regulated by FDA as a veterinary product.

amoxicillin trihydrate is found on the following regulatory lists
Not applicable

microcrystalline cellulose is found on the following regulatory lists
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS), US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2, US - Massachusetts - Right To Know Listed Chemicals, US NIOSH Recommended Exposure Limits (RELs), US OSHA Permissible Exposure Limits (PELs) Table Z-1, US OSHA Permissible Exposure Limits (PELs) Table Z-3, US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

potassium clavulanate is found on the following regulatory lists
Not applicable

sodium starch glycolate is found on the following regulatory lists
US TSCA - Chemical Substance Inventory

magnesium stearate is found on the following regulatory lists
International WHO List of Proposed OEL MNMS, US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2, US - Massachusetts - Right To Know Listed Chemicals, US NIOSH RELs, US OSHA PELs Table Z-1, US OSHA PELs Table Z-3, US TSCA - Chemical Substance Inventory

hypromellose E5 is found on the following regulatory lists
US TSCA - Chemical Substance Inventory

colloidal silicon dioxide is found on the following regulatory lists
Chemical Footprint Project - Chemicals of High Concern List, International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs, MMMS, US - California - Biomonitoring - Priority Chemicals, US - California Proposition 65 – Carcinogens, US - California Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65 List, US - Massachusetts - Right To Know Listed Chemicals, US DOE Temporary Emergency Exposure Limits (TEELs), US NIOSH Carcinogen List, RELs, US OSHA Carcinogens Listing, PELs Table Z-1, PELs Table Z-3, US TSCA - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

titanium dioxide is found on the following regulatory lists
Chemical Footprint Project - Chemicals of High Concern List, International Agency for Research on Cancer (IARC) - Agents Classified bythe IARC Monographs, International Agency for Research on Cancer (IARC) - Agents Classified bythe IARC Monographs - Group 2B: Possibly carcinogenic to humans , MMMS, US - California Proposition 65 – Carcinogens, US - California Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65 List, US – Massachusetts - Right To Know Listed Chemicals, TLV, TLV – Carcinogens, TLV – Notice of Intended Changes, US DOE TEELs, US List of Active Substances Exempt from the TSCA Inventory Notifications(Active-Inactive) Rule, US NIOSH Carcinogen List, RELs, PELs Table Z-1, PELs Table Z-3, US TSCA - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

polyethylene glycol 6000 is found on the following regulatory lists
US AIHA Workplace Environmental Exposure Levels (WEELs), TEELs, US TSCA - Chemical Substance Inventory, US Toxicology Excellence for Risk Assessment (TERA) Workplace Environmental Exposure Levels (WEEL), US TSCA

Chemical Substance Inventory - Interim List of Active Substances

iron oxide yellow is found on the following regulatory lists
International WHO List of Proposed OEL MNMS, US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2, US - Massachusetts - Right To Know Listed Chemicals, US NIOSH RELs, US OSHA PELs Table Z-1, US OSHA PELs Table Z-3, US TSCA - Chemical Substance Inventory

Federal Regulations	
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Section 311/312 hazard categories	
Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	Yes
Acute toxicity (any route of exposure)	No
Reproductive toxicity	No
Skin Corrosion or Irritation	Yes
Respiratory or Skin Sensitization	Yes
Serious eye damage or eye irritation	Yes
Specific target organ toxicity (single or repeated exposure)	Yes
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)
None Reported

State Regulations
US. California Proposition 65

WARNING: This product can expose you to chemicals including **colloidal silicon dioxide, titanium dioxide**, which are known to the State of California to causecancer. For more information, go to www.P65Warnings.ca.gov.

National Inventory Status	
Australia - AIIC / Australia Non-Industrial Use	No (potassium clavulanate)
Canada - DSL	No (potassium clavulanate)
Canada - NDSL	No (amoxycillin trihydrate; potassium clavulanate; sodium starch glycolate; magnesium stearate; hydroxypropyl methylcellulose; polyethylene glycol 6000; talc; C.I. iron oxide yellow)
China - IECSC	No (amoxycillin trihydrate; potassium clavulanate)
Europe - EINEC / ELINCS /NLP	No (sodium starch glycolate; hydroxypropyl methylcellulose)
Japan - ENCS	No (amoxycillin trihydrate; potassium clavulanate)
Korea - KECI	No (potassium clavulanate)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (potassium clavulanate)
USA - TSCA	No (amoxycillin trihydrate; potassium clavulanate)
Taiwan - TCSI	Yes
Mexico - INSQ	No (potassium clavulanate; polyethylene glycol 6000)
Vietnam - NCI	Yes
Russia - FBEPH	No (amoxycillin trihydrate; potassium clavulanate; iron oxide yellow)

Yes = All CAS declared ingredients are on the inventory
No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will requireregistration

SECTION 16: OTHER INFORMATION

Initial date: June 2023 – Classification, Product name updated from Clavacillin™ (amoxicillin trihydrate/clavulanate potassium) Veterinary Tablets to Clavacillin® (amoxicillin and clavulanate potassium tablets), USP Veterinary Tablets

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.

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
IDLH: Immediately Dangerous to Life or Health Concentrations
AIIC: Australian Inventory of Industrial Chemicals
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
ENCS: Existing and New Chemical Substances Inventory
PICCS: Philippine Inventory of Chemicals and Chemical Substances
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances
NZIoC: New Zealand Inventory of Chemicals

STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit
ES: Exposure Standard
OSF: Odor Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odor Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
NLP: No-Longer Polymers
KECI: Korea Existing Chemicals Inventory
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory

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