SAFETY DATA SHEETS

This SDS packet was issued with item:

078937198

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 078936858 078937224 078938015 078944764 078944769 078944797 078945422 078945455 078945456 078945457 078950117 078950401

SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name	Clavacillin™ (amoxicillin trihydrate/clavulanate potassium) Veterinary Tablets
Synonyms	Amoxicillin Trihydrate and Clavulanate Potassium Tablets
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	Oral tablet / antibiotic. For professional use only
Uses advised against	Not for human use
1.3 Details of the supplier of the substance or mixture	
Registered company name	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: HAZARDS 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, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2A, Sensitisation (Respiratory) Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, Carcinogenicity Category 1A

2.2 Label elements

Hazard pictogram(s)	
Signal word	**Danger**

2.3 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.
2.4 Precautionary statement(s) Prevention	
P201	Obtain special instructions before use.
P261	Avoid breathing dust/fumes.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves and 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.
2.5 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.
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.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
2.6 Precautionary statement(s) Storage	
P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
2.7 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 THE 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	hypromellose E5
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

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician if irritation persist.

Skin contact:
Immediately remove all contaminated clothing, including footwear. Wash off with soap and plenty of water. Consult a physician if irritation persist.

Inhalation:
The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Ingestion:
If swallowed do **NOT** induce vomiting. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed
See Section 11

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

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable 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 equipment and precautions for fire-fighters:

Fire Fighting	Firefighters should wear inhalation protection as hazardous substances from the fire may be adsorbed on the silica particles. 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 fire fighting procedures suitable for surrounding area. **DO NOT** approach containers suspected to be hot. Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	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.
Major Spills	Alert Emergency Services and tell them location and nature of hazard. Control personal contact by wearing protective clothing. 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. **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. 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. Observe manufacturer's storage and handling recommendations contained within this SDS. For major quantities.

7.2 Conditions for safe storage, including any incompatibilities

Suitable container	Tablets are packaged in foil strip packs.
Storage incompatibilities	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.

7.3 Specific end use(s)

Antibacterial. For professional use only. Federal (U.S.A.) law restricts this drug to be used by or on the order of a licensed veterinarian.

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 / 15 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3		Inert or Nuisance Dust: Total Dust	15 mg/m^3 / 50 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1		Cellulose- Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1		Cellulose- Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available
US NIOSH		Cellulose - total	10 mg/m^3	Not	Not	Not

Recommended Exposure Limits (RELs)				Available	Available	Available
US NIOSH Recommended Exposure Limits (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 Permissible Exposure Limits (PELs) Table Z-3	magnesium stearate	Inert or Nuisance Dust: Respirable fraction	5 mg/m^3 / 15 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3		Inert or Nuisance Dust: Total Dust	15 mg/m^3 / 50 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1		Particulates Not Otherwise Regulated (PNOR)- Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1		Particulates Not Otherwise Regulated (PNOR)- Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)		Particulates not otherwise regulated	Not Available	Not Available	Not Available	See Appendix D
US ACGIH Threshold Limit Values (TLV)		Stearates (Inhalable particulate matter)	10 mg/m^3	Not Available	Not Available	A4
US ACGIH Threshold Limit Values (TLV)		Stearates (Respirable particulate matter)	3 mg/m^3	Not Available	Not Available	A4
US OSHA Permissible Exposure Limits (PELs) Table Z-3	colloidal silicon dioxide	Amorphous, including natural diatomaceous earth	80 (%SiO2) mg/m^3 / 20 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1		Particulates Not Otherwise Regulated (PNOR)- Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1		Particulates Not Otherwise Regulated (PNOR)- Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)		Silica, amorphous	6 mg/m^3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (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 Permissible Exposure Limits (PELs) Table Z-3		Inert or Nuisance Dust: Respirable fraction	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 Recommended Exposure Limits (RELs)		Titanium dioxide	Not Available	Not Available	Not Available	Ca; See Appendix A
US ACGIH Threshold Limit Values (TLV)		Titanium dioxide	10 mg/m^3	Not Available	Not Available	(A4)
US OSHA Permissible Exposure Limits (PELs) Table Z-3	talc	Silicates (less than 1% crystalline silica): Soapstone	20 mppcf	Not Available	Not Available	Not Available

US OSHA Permissible Exposure Limits (PELs) Table Z-3		Silicates (less than 1% crystalline silica): Talc (containing asbestos)	Not Available	Not Available	Not Available	Use asbestos limit
US OSHA Permissible Exposure Limits (PELs) Table Z-3		Silicates (less than 1% crystalline silica): Talc (not containing asbestos)	20 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1		Particulates Not Otherwise Regulated (PNOR)- Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1		Particulates Not Otherwise Regulated (PNOR)- Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)		Talc (containing no asbestos and less than 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 Threshold Limit Values (TLV)		Talc: Containing no asbestos fibers (Respirable particulate matter)	2 mg/m3	Not Available	Not Available	A4
US OSHA Permissible Exposure Limits (PELs) Table Z-3	iron Oxide Yellow	Inert or Nuisance Dust: Respirable fraction	5 mg/m^3 / 15 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3		Inert or Nuisance Dust: Total Dust	15 mg/m^3 / 50 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1		Particulates Not Otherwise Regulated (PNOR)- Total dust	15 mg/m^3	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1		Particulates Not Otherwise Regulated (PNOR)- Respirable fraction	5 mg/m^3	Not Available	Not Available	Not Available
US NIOSH Recommended Exposure Limits (RELs)		Particulates not otherwise regulated	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/m3	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

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	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	
Hand/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 watch-bands should be removed and destroyed.
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.
Skin and body protection	Wear suitable protective clothing if skin contact with drug product is possible. See Hand protection above.
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 should be buttoned at collar and cuffs. For over 1 kg and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. Eye wash unit and ready access to an emergency shower. For Emergencies: Vinyl suit
Respiratory protection	Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, 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 (degrees C):** Not Available **Initial boiling point and boiling range:** Not Available **Flash point:** Not Applicable **Evaporation rate:** Not Available **Flammability:** Not Available **Upper / lower flammability or explosive limits:** Not Available **Vapor pressure:** Not Available **Relative density (at degrees C):** Not Available **Solubility in water and solvents (mg/l):** Not Available	**Vapor density:** Not Available **Auto ignition temperature (degrees C):** Not Applicable **Decomposition temperature (degrees C):** Not Available **Viscosity (degrees C):** Not Available **Explosive properties:** None **Oxidizing properties:** None **Partition coefficient:** Not Available **Molecular weight:** Not Applicable **Taste:** Not Available **Surface tension:** Not Available **Volatile component:** Not Available **Gas group:** Not Available **pH as a solution:** Not Available **VOC g/L:** Not Available **Specific gravity @ 20 degrees C (water = 1):** Not Available

10: REACTIVITY AND STABILITY

Reactivity	Hazardous reactions will not occur under normal conditions.
Chemical stability	Stable under recommended handling and storage conditions.
Possibility of hazardous reactions	Stable under recommended handling and storage conditions.
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	Decomposition will not occur under normal conditions

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Inhaled	Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial number of individuals, following inhalation.
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual.
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.
Eye	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.

Chronic	On the basis of epidemiological data, it has been concluded that prolonged inhalation of the material, in an occupational setting, is likely to produce cumulative health effects and may produce cancer in humans.	
Clavacillin (amoxicillin trihydrate/clavulanate potassium) 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]	Eye: no adverse effect observed (not irritating) [1]

	Oral(rat) LD_{50} >5000 mg/kg[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 Eye Damage/Irritation	✓	**STOT - Single Exposure**	✓
Respiratory or Skin sensitisation	✓	**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 trihydrate/ clavulanate potassium) 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

		Not Available	Not Available		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.

Very 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: 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:

DO NOT allow wash water from cleaning or process equipment to enter drains. Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Consult State Land Waste Authority for disposal. Bury or incinerate residue at an approved site. Recycle containers if possible, or dispose of in an authorised landfill.

SECTION 14: TRANSPORT INFORMATION

Labels required

Marine pollutant:	NO

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

Not available

Transport in bulk in accordance with the ICG Code

Not available

SECTION 15: REGULATORY INFORMATION

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

amoxicillin trihydrate
Not applicable

microcrystalline cellulose
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS), US - Massachusetts - Right To Know Listed Chemicals, US ACGIH Threshold Limit Values (TLV), US List of Active Substances Exempt from the TSCA Inventory Notifications (Active-Inactive) Rule, 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, US TSCA Chemical Substance Inventory - Interim List of Active Substances

potassium clavulanate
Not applicable

sodium starch glycolate
US List of Active Substances Exempt from the TSCA Inventory Notifications (Active-Inactive) Rule, US TSCA - Chemical Substance Inventory

magnesium stearate
TLV, TLV – Carcinogens, RELs, PELs Table Z-1, PELs Table Z-3, US TSCA - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

hypromellose E5
US TSCA - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

colloidal silicon dioxide
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
Chemical Footprint Project - Chemicals of High Concern List, 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 , 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
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
RELs, PELs Table Z-1, PELs Table Z-3, US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

15.2 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	No
Specific target organ toxicity (single or repeated exposure)	No
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 **silica amorphous, titanium dioxide**, which are known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

National Inventory Status:

National Inventory	Status
Austrália – AICS / Australia Non-Industrial Use	No (potassium clavulanate)
Canada – DSL	No (potassium clavulanate)
Canada – NDSL	No (amoxycillin trihydrate; potassium clavulanate; sodium starch glycolate; magnesium stearate; hypromellose E5; polyethylene glycol 6000; talc; iron oxide yellow)
China – IECSC	No (amoxycillin trihydrate; potassium clavulanate)
Europe - EINEC / ELINCS / NLP	No (sodium starch glycolate; hypromellose E5)
Japan – ENCS	No (amoxycillin trihydrate; cellulose; 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 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

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