SAFETY DATA SHEETS

This SDS packet was issued with item:

078950117

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 078937198 078937224 078938015 078944764 078944769 078944797 078945422 078945455 078945456 078945457 078950401

SECTION 1: Identification

1.1 Product identifier	
Product name	Clavacillin (amoxicillin and clavulanate potassium for oral suspension), USP Drops
Chemical name	Not Applicable
Synonyms	Not Available
Chemical formula	Not Applicable
Other means ofidentification	Not Available
1.2 Recommended use of the chemical and restrictions on use	
Relevant identified uses	Oral antibiotic drops for dogs and cats. Not for human use.
1.3 Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party	
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, 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, Specific Target Organ Toxicity - Repeated Exposure Category 2, Hazardous to the Aquatic Environment Long-Term Hazard Category 3
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.
H373	May cause damage to organs through prolonged or repeated exposure.
H412	Harmful to aquatic life with long lasting effects.
Hazard(s) not otherwise classified	Not Applicable
Precautionary statement(s) Prevention	
P260	Do not breathe dust/fume.
P261	Avoid breathing dust/fumes.
P271	Use only outdoors or in a well-ventilated area.
P284	[In case of inadequate ventilation] wear respiratory protection.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
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.
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	30-40	amoxicillin trihydrate
61177-45-5	10-15	clavulanate potassium
proprietary	proprietary	cellulose
proprietary	proprietary	silicon dioxide (silica precipitated)
proprietary	proprietary	sodium saccharin

The specific chemical identity and/or 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, aerosols 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.
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

When cutaneous reactions to penicillin occur, they may subside spontaneously within a few hours or days following withdrawal of the antibiotic. Administration of antihistamines, or in the absence of a response, corticosteroids, may control reactions.

Treatment of penicillin overdose may include: Perform gastric decontamination in cases of severe ingestion. Administer activated charcoal as a slurry. Manage anaphylaxis with establishment of patent airway, epinephrine, and diphenhydramine. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital. [Meditext 2007 and PDR 2007]

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 suitable for surrounding area.

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. Prevent, by any means available, spillage from entering drains or water course. Use water delivered as a fine spray to control fire and cool adjacent area. 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	Combustible solid which burns but propagates flame with difficulty. 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. Build-up of electrostatic charge may be prevented by bonding and grounding. Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting. Combustion products include carbon monoxide, carbon dioxide, nitrogen/sulfur/silicon oxides, other pyrolysis products typical of burning organic material. May emit clouds of poisonous/corrosive fumes.

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	Minor hazard. Clear area of personnel. Alert Fire Brigade and tell them location and nature of hazard. Control personal contact with the substance, by using protective equipment as required. Prevent spillage from entering drains or water ways. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal. Wash area and prevent runoff into drains or waterways. 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. Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source. Do NOT cut, drill, grind or weld such containers. In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.
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. 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	Glass container is suitable for laboratory quantities Polyethylene or polypropylene container. Check all containers are clearly labelled and free from leaks.
Storage incompatibility	Avoid strong acids, bases. Avoid reaction with oxidising agents

SECTION 8: Exposure controls / personal protection

8.1 Control parameters

Occupational exposure limits (OEL)

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

US OSHA PELs Table Z-3	silicon dioxide (silica precipitated)	Inert or Nuisance Dust: Total Dust	5 mg/m^3 / 15 mppcf	Not Available	Not Available	Not Available
US NIOSH RELs	silicon dioxide (silica precipitated)	PNOR	Not Available	Not Available	Not Available	Not Available

Emergency limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
silicon dioxide (silica precipitated)	18 mg/m^3	200 mg/m^3	1,200 mg/m^3

Ingredient	Original IDLH	Revised IDLH
Not Available for any ingredient	Not Available for any ingredient	Not Available for any ingredient

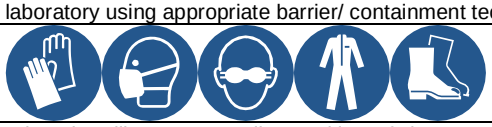
Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
amoxicillin trihydrate	E	≤ 0.01 mg/m³
clavulanate potassium	E	≤ 0.01 mg/m³

Notes: Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical'spotency 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.

MATERIAL DATA

8.2 Exposure controls

Appropriate engineering controls	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/transferring quantities exceeding 500 mg. When handling quantities up to 500 g in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kg may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kg should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology.
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: Use chemical goggles [AS/NZS 1337.1, EN166 or national equivalent]. Face shield. Full face shield may be required for supplementary but never for primary protection of eyes. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants.
Skin protection	See Hand/feet 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 watch-bands should be removed and destroyed. The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).
Body protection	See Other protection below.
Other protection	For quantities up to 500 g a laboratory coat may be suitable. For quantities up to 1 kg a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kg and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection. Eye wash unit. Ensure there is 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)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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

SECTION 10: Stability and reactivity

Reactivity	See Section 7
Chemical stability	Product is considered stable. Hazardous polymerization will not occur. Unstable in the presence of incompatible materials.
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

Information on toxicological effects

Inhalation	May produces irritation of the respiratory system, in a substantial number of individuals, following inhalation.
Ingestion	In the case of accidental oral intake, seek medical advice immediately and show the package leaflet. Ingestion may cause nausea, vomiting abdominal irritation, and pain.
Skin contact	The material may produce mild inflammation of the skin in a substantial number of individuals following direct contact.
Eye contact	Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.
Chronic	Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Practical evidence shows that inhalation of the material is capable of inducing a sensitisation reaction in a substantial number of individuals at a greater frequency than would be expected from the response of a normal population. Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance.

Clavacillin (amoxicillin and clavulanate potassium for oral suspension), USP Drops	**Toxicity**	**Irritation**
	Not Available	Not Available
amoxicillin trihydrate	**Toxicity**	**Irritation**
	dermal (rat) LD_{50}: >2000 mg/kg[1] Oral (rat) LD_{50}; >2000 mg/kg[1]	Not Available
clavulanate potassium	**Toxicity**	**Irritation**
	Oral (mouse) LD_{50}; 4526 mg/kg[2]	Not Available
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
silicon dioxide (silica precipitated)	**Toxicity**	**Irritation**
	Not Available	Eye (rabbit) : 8.3 mg/48h
sodium saccharin	**Toxicity**	**Irritation**
	Oral (rat) LD_{50}; >14200 mg/kg[2]	Eye: no adverse effect observed (not irritating) [1] Skin: no adverse effect observed (not irritating) [1]

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

Clavacillin (amoxicillin and clavulanate potassium for oral suspension), USP Drops	**Endpoint**	**Test Duration**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
amoxicillin trihydrate	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**
	EC50	72h	Algae or other aquatic plants	56.3mg/l	4
	EC50	48h	Crustacea	>1000mg/l	2
	EC50	96h	Algae or other aquatic plants	0.002mg/l	2
	LC50	96h	Fish	>100mg/l	2
	NOEC(ECx)	96h	Algae or other aquatic plants	0.001mg/l	2
clavulanate potassium	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
cellulose	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available
silicon dioxide (silica	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**

precipitated)	Not Available	Not Available	Not Available	Not Available	Not Available
sodium saccharin	**Endpoint**	**Test duration**	**Species**	**Value**	**Source**
	EC50	72h	Algae or other aquatic plants	>100mg/l	2
	EC50	48h	Crustacea	>100mg/l	2
	EC50	96h	Algae or other aquatic plants	15.838mg/l	2
	ErC50	72h	Algae or other aquatic plants	187mg/l	2
	LC50	96h	Fish	>400mg/l	2
	EC50(ECx)	336h	Crustacea	4.4mg/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

Harmful 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
amoxicillin trihydrate	HIGH	HIGH
cellulose	LOW	LOW
silicon dioxide (silica precipitated)	LOW	LOW
sodium saccharin	HIGH	HIGH

12.3 Bioaccumulative potential

Ingredient	Bioaccumulation
amoxicillin trihydrate	LOW (LogKOW = 0.87)
cellulose	LOW (LogKOW = -5.1249)
silicon dioxide (silica precipitated)	LOW (LogKOW = 0.5294)
sodium saccharin	LOW (LogKOW = 0.4488)

12.4 Mobility in soil

Ingredient	Mobility
amoxicillin trihydrate	LOW (KOC = 865.5)
cellulose	LOW (KOC = 10)
silicon dioxide (silica precipitated)	LOW (KOC = 23.74)
sodium saccharin	LOW (KOC = 32.13)

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. 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

Land 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 the ICG Code

Product name	Ship type
	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

clavulanic acid is found on the following regulatory lists
Not Applicable

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-2.5, US - Massachusetts - Right To Know Listed Chemicals, US NIOSH Recommended Exposure Limits (RELs), US OSHA Permissible Exposure Limits (PELs) Table Z-1, US OSHA PELs Table Z-3, US TSCA - Chemical Substance Inventory

Silicon dioxide (silica precipitated) is found on the following regulatory lists

International WHO List of Proposed OEL Values for MNMS, US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2.5, US - Massachusetts - Right To Know Listed Chemicals, US DOE Temporary Emergency Exposure Limits (TEELs), US NIOSH RELs, US OSHA PELs Table Z-1, US OSHA PELs Table Z-3

Sodium saccharin is found on the following regulatory lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic, US - Massachusetts - Right To Know Listed Chemicals, 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	No
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
Not Reported

National Inventory Status	
Australia - AIIC / Australia Non-Industrial Use	No (clavulanate potassium)
Canada - DSL	No (clavulanate potassium)
Canada - NDSL	No (amoxicillin trihydrate; clavulanate potassium; silicon dioxide (silica precipitated); sodium saccharin)
China - IECSC	No (amoxicillin trihydrate; clavulanate potassium)
Europe - EINEC / ELINCS /NLP	No (silicon dioxide (silica precipitated))
Japan - ENCS	No (amoxicillin trihydrate; clavulanate potassium; sodium saccharin)
Korea - KECI	No (clavulanate potassium)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (clavulanate potassium)
USA - TSCA	No (amoxicillin trihydrate; clavulanate potassium; silicon dioxide (silica precipitated))
Taiwan - TCSI	Yes
Mexico - INSQ	No (clavulanate potassium)
Vietnam - NCI	Yes
Russia - FBEPH	No (amoxicillin trihydrate; clavulanate potassium)

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

Revision Date: August 2023 Product name change, Classification change due to full database hazard calculation/update

Initial date: June 2021 – Classification

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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