


SDS according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

| SECTION 1: IDENTIFICATION | |
|---|---|
| 1.1 Product identifier | |
| Product name | Amoxicillin and Clavulanate Potassium for Oral Suspension |
| Synonyms | None |
| Proper shipping name | N/A |
| Other means of identification | None |
| 1.2 Relevant identified uses of the substances or mixture and uses advised against | |
| Relevant identified uses | Oral antibiotic drops for dogs and cats. For professional use only. |
| Uses advised against | Not for human use. Keep out of reach of children and animals. |
| 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 |
| Website | www.dechra-us.com |
| Email | support@dechra.com |
| 1.4 Emergency telephone numbers | |
| Dechra (US) | 866-933-2472 |

| SECTION 2: HAZARDS IDENTIFICATION | |
|---|---|
| 2.1 Classification of the substance or mixture | |
| Poisons schedule | S4 |
| Classification ^[1] | Skin Corrosion/Irritation Category 2, Skin Sensitizer Category 1, Eye Irritation Category 2A, Respiratory Sensitizer Category 1, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Acute Aquatic Hazard Category 3, Chronic Aquatic Hazard Category 3 |
| 1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI | |
| 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. |
| H412 | Harmful to aquatic life with long lasting effects. |
| Supplementary statement(s) N/A | |
| Precautionary statement(s) prevention: | |
| P261 | Avoid breathing dust/fumes. |
| P271 | Use only outdoors or in a well-ventilated area. |
| P280 | Wear protective gloves and clothing, eye and face protection. |
| P284 | [In case of inadequate ventilation] wear respiratory protection. |
| P273 | Avoid release to the environment. |
| P264 | Wash all exposed external body areas thoroughly after handling. |
| P272 | Contaminated work clothing should not be allowed out of the workplace. |
| Precautionary statement(s) response | |
| P304+P340 | IF INHALED: Remove person to fresh air, keep breathing comfortable. |
| P342+P311 | If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician/first aider. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| 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. |

| | |
|---|--|
| 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 authorized hazardous or special waste collection point in accordance with any local regulation. |

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See 'Composition on ingredients' in Section 3.2

3.2 Mixtures

| CAS No | % w/w | 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 | saccharin sodium |
| N/A | balance | ingredients determined not to be hazardous |

1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOELVs available

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

| | |
|---------------------|---|
| Eye contact | Accidental exposure to the eyes should be washed out immediately with plenty of water. Seek medical advice and show the package leaflet or the label to the medical practitioner. |
| Skin contact | Accidental exposure to on the skin should be washed off with plenty of soap and water. Remove contaminated clothes that are in direct contact with skin. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner. |
| Inhalation | If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested. |
| Ingestion | If swallowed, do not induce vomiting. Seek medical advice immediately and show the package leaflet or the label to the medical practitioner. |


4.2 Indication of immediate medical attention and special treatment needed

Treat symptomatically.

| SECTION 5: FIRE FIGHTING MEASURES | |
|--|---|
| 5.1 Extinguishing media | |
| Suitable | Select extinguishing media suitable for surrounding area. |
| Unsuitable | There is no restriction on the type of extinguisher which may be used. |
| 5.2 Special hazards arising from the substance or mixture | |
| Fire incompatibility | Avoid contamination with oxidising agents – nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result |
| 5.3 Special protective actions for fire-fighters: | |
| Firefighting | Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. DO NOT approach containers suspected to be hot. Equipment should be thoroughly decontaminated after use. |
| Fire / explosion hazard | Combustible solid which burns but propagates flame with difficulty. May emit poisonous and/or corrosive fumes. |
| HAZCHEM | N/A |

| 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 all spills immediately. Avoid breathing vapors and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Place in a suitable, labelled container for waste disposal. Flush spill area with water. |
| Major spills | Clear area of personnel and move upwind. Alert the fire department about the nature/Location of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent spillage from entering drains or watercourse. |

| 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. DO NOT eat, drink or smoke when handling the product. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations. |
| Other information | Store in original containers. Keep containers securely sealed. Keep out of the reach and sight of children. |
| 7.2 Conditions for safe storage, including any incompatibilities | |
| Suitable container | 22 mL bottles |
| 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) | | | |
| N/A | | | |
| EMERGENCY LIMITS: | | | |
| Ingredient | TEEL-1 | TEEL-2 | TEEL-3 |
| silica precipitated | 18 mg/m ³ | 200 mg/m ³ | 1,200 mg/m ³ |
| Ingredient | Original IDLH | | Revised IDLH |
| N/A for any ingredient | | | |
| OCCUPATIONAL EXPOSURE BANDING | | | |
| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit | |
| amoxicillin | E | ≤ 0.01 mg/m ³ | |
| Notes: 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 | None under normal operating conditions. Enclosed local exhaust ventilation is required at points of dust, fume, or vapor generation. | | |
| Personal protection | None for handling small quantities. When using large quantities:  | | |
| Eye and face protection | No special equipment needed when handling small quantities. OTHERWISE: Wear chemical goggles, face shield. | | |
| Skin protection | No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective clothing. | | |
| Hands / feet protection | See skin protection above. | | |
| Body protection | Wear appropriate clothing. | | |
| Other protection | No special equipment needed when handling small quantities. | | |
| Thermal hazards | N/A | | |
| Respiratory protection | N/A | | |
| 8.3 Environmental exposure controls | | | |
| See Section 12. | | | |

| SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES | |
|---|--|
| 9.1 Information on basic physical and chemical properties | |
| <p>Appearance: White to light yellow powder with some yellow grains. Forms a white to light yellow suspension in water</p> <p>Container: 22 mL bottle</p> <p>Physical state: Powder</p> <p>Odor: N/A</p> <p>Odor threshold: N/A</p> <p>pH (as supplied): N/A</p> <p>Melting point / freezing point (°C): N/A</p> <p>Initial boiling point and boiling range: N/A</p> <p>Flash point: N/A</p> <p>Evaporation rate: N/A</p> <p>Flammability: N/A</p> <p>Upper/Lower flammability or explosive limits: N/A</p> <p>Vapor pressure: N/A</p> <p>Relative density (at °C): N/A</p> | <p>Solubility in water and solvents (mg/L): Partly miscible in water</p> <p>Vapor density: N/A</p> <p>Auto ignition temperature (°C): N/A</p> <p>Decomposition temperature (°C): N/A</p> <p>Viscosity (°C): N/A</p> <p>Explosive properties: N/A</p> <p>Oxidizing properties: N/A</p> <p>Partition coefficient: N/A</p> <p>Molecular weight: N/A</p> <p>Taste: N/A</p> <p>Surface tension: N/A</p> <p>Volatile component: N/A</p> <p>Gas group: N/A</p> <p>pH as a solution: N/A</p> <p>VOC g/L: N/A</p> <p>Specific gravity @ 20°C (water = 1): N/A</p> |

| 10: REACTIVITY AND STABILITY | |
|--|--|
| 10.1 Reactivity | See Section 7. |
| 10.2 Chemical stability | Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur. |
| 10.3 Possibility of hazardous reactions | See Section 7. |
| 10.4 Conditions to avoid | See Section 7. |
| 10.5 Incompatible materials | See Section 7. |
| 10.6 Hazardous composition | See Section 5. |

| SECTION 11: TOXICOLOGICAL INFORMATION | | | |
|---|---|---|---|
| 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 | May cause skin irritation. | | |
| Eye contact | May cause eye irritation. | | |
| Chronic | Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. | | |
| Amoxicillin and Clavulanate Potassium for Oral Suspension | Toxicity | Irritation | |
| | N/A | N/A | |
| amoxycillin | Toxicity | Irritation | |
| | Dermal (rat) LD ₅₀ : >2000 mg/kg ^[1] Oral(Rat) LD ₅₀ ; >2000 mg/kg ^[1] | N/A | |
| clavulanate potassium | Toxicity | Irritation | |
| | Oral (Dog) LD ₅₀ ; 326 mg/kg ^[2] | N/A | |
| 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] | N/A | |
| Silica precipitated | Toxicity | Irritation | |
| | N/A | Eye (rabbit) : 8.3 mg/48h | |
| Saccharin sodium | Toxicity | Irritation | |
| | Oral(Rat) LD ₅₀ ; 1280 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 N/A or does not fill the criteria for classification ✓ - Data available to make classification | | | |

SECTION 12: ECOLOGICAL INFORMATION

| 12.1 Toxicity | | | | | |
|--|-------------------------------------|--------------------|-------------------------------|------------|--------|
| | Endpoint | Test Duration (hr) | Species | Value | Source |
| Amoxicillin and Clavulanate Potassium for Oral Suspension | N/A | N/A | N/A | N/A | N/A |
| amoxycillin | EC ₅₀ | 96h | Algae or other aquatic plants | 0.002mg/L | 2 |
| | EC ₅₀ | 72h | Algae or other aquatic plants | 56.3mg/L | 2 |
| | LC ₅₀ | 96h | Fish | >100mg/L | 2 |
| | EC ₅₀ | 48h | Crustacea | >1000mg/L | 2 |
| | NOEC(EC _x) | 96h | Algae or other aquatic plants | 0.001mg/L | 2 |
| clavulanate potassium | N/A | N/A | N/A | N/A | N/A |
| cellulose | N/A | N/A | N/A | N/A | N/A |
| Silica precipitated | N/A | N/A | N/A | N/A | N/A |
| Saccharin sodium | EC ₅₀ | 72h | Algae or other aquatic plants | 187mg/L | 2 |
| | EC ₅₀ | 48h | Crustacea | >100mg/L | 2 |
| | LC ₅₀ | 96h | Fish | >400mg/L | 2 |
| | EC ₅₀ (EC _x) | 336h | Crustacea | 4.4mg/L | 2 |
| | EC ₅₀ | 96h | Algae or other aquatic plants | 15.838mg/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

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|----------------------------|-------------------------|------------------|
| amoxycillin | High | High |
| cellulose | Low | Low |
| silica precipitated | Low | Low |
| saccharin sodium | High | High |

12.3 Bioaccumulative potential

| Ingredient | Bioaccumulation |
|----------------------------|------------------------|
| amoxycillin | Low (LogKOW = 0.87) |
| cellulose | Low (LogKOW = -5.1249) |
| silica precipitated | Low (LogKOW = 0.5294) |
| saccharin sodium | Low (LogKOW = 0.4488) |

| 12.4 Mobility in soil | |
|-----------------------|-------------------|
| Ingredient | Bioaccumulation |
| amoxicillin | Low (KOC = 865.5) |
| cellulose | Low (KOC = 10) |
| silica precipitated | Low (KOC = 23.74) |
| saccharin sodium | Low (KOC = 32.13) |

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

| | |
|-------------------------------------|---|
| Product / packaging disposal | Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements. |
| Waste treatment options | DO NOT allow wash water from cleaning or process equipment to enter drains. Contact the local authorities. |
| Sewage disposal options | Consider local laws and regulations. |

SECTION 14: TRANSPORT INFORMATION

Labels required:

| | |
|--------------------------|-----|
| Marine pollutant: | No |
| HAZCHEM | N/A |

Land transport (ADG):

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

N/A

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

N/A

Transport in bulk in accordance with ICG Code:

N/A

SECTION 15: REGULATORY INFORMATION

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

Product regulated by FDA as a veterinary product.

SECTION 16: OTHER INFORMATION

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average
PC – STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit,
IDLH: Immediately Dangerous to Life or Health Concentrations
ES: Exposure Standard
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
ENCS: Existing and New Chemical Substances Inventory
TSCA: Toxic Substances Control Act
NCI: National Chemical Inventory
N/A: Not applicable, not available

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