SAFETY DATA SHEET

CopperMax

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	23.06.2020	122000008228	Date of first issue: 23.06.2020

Section 1: Identification

1.1 Product identifier

CopperMax

ACVM number : A009469

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

Use of the Substance/Mixture : Veterinary medicine

1.3 Details of the supplier of the safety data sheet

Company
Elanco New Zealand
88 Shortland Street
1010 AUCKLAND
NEW ZEALAND
+64 0800 352 626
elanco_sds@elanco.com

1.4 Emergency telephone number

In case of emergency: CHEMTREC International: +1 703-527-3887 (24 hours)
or +64-98010034 (local)

Section 2: Hazard identification

GHS Classification

Not a dangerous substance / mixture according to GHS.

GHS label elements

Not a dangerous substance / mixture according to GHS.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Calcium Copper Edetate	66317-91-7	>= 30 -< 50
Methyl 4-hydroxybenzoate	99-76-3	>= 0,1 -< 0,25

Section 4: First-aid measures

General advice	:	Take off all contaminated clothing immediately.
If inhaled	:	Remove to fresh air. Call a physician immediately.
In case of skin contact	:	After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.
In case of eye contact	:	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
If swallowed	:	Clean mouth with water and drink afterwards plenty of water. Call a physician immediately.
Most important symptoms and effects, both acute and delayed	:	No information available.
Notes to physician	:	No information available.

Section 5: Fire-fighting measures

Suitable extinguishing media	:	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire-fighting	:	Fire may cause evolution of: Carbon monoxide (CO) Carbon dioxide (CO2)
Specific extinguishing methods	:	Prevent fire extinguishing water from contaminating surface water or the ground water system.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Use with adequate ventilation.
Environmental precautions	:	Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Suppress (knock down) gases/vapours/mists with a water spray jet. Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Place in closed containers. Label for proper disposal.

Section 7: Handling and storage

Advice on protection against fire and explosion	:	No special protective measures against fire required.
Advice on safe handling	:	Industrial uses: Avoid formation of aerosol. Use with local exhaust ventilation. Avoid contact with skin, eyes and clothing.
Hygiene measures	:	Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!
Conditions for safe storage	:	For storage suitable stores with adequate product-reception volume must be used. During handling local official regulations must be observed in order to avert impairment of water by the product. To preserve quality, protect from temperatures above +30 °C.

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection	:	In the case of vapour formation use a respirator with an approved filter. In the case of vapour formation use a respirator with an approved filter.
Hand protection		
Material	:	Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear
Remarks	:	Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.
Eye protection	:	Safety glasses
Protective measures	:	No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients. For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet. The personal protective equipment is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components

can be expected.
Wear suitable protective equipment.

Section 9: Physical and chemical properties

Appearance	:	liquid
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Impact sensitivity	:	No data available
Minimum ignition energy	:	No data available

Section 10: Stability and reactivity

Reactivity	:	No data available
Chemical stability	:	No data available
Possibility of hazardous reactions	:	No data available
Conditions to avoid	:	No data available
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	Carbon monoxide (CO) Carbon dioxide (CO2)

Section 11: Toxicological information

Skin corrosion/irritation

Components:

Methyl 4-hydroxybenzoate:

Species	:	Rabbit
Exposure time	:	24 h
Result	:	No skin irritation

Serious eye damage/eye irritation

Components:

Methyl 4-hydroxybenzoate:

Species	:	Rabbit

Result : Mild eye irritation
Assessment : The available study results do not lead to a GHS classification

Respiratory or skin sensitisation

Components:

Methyl 4-hydroxybenzoate:

Test Type : Skin sensitisation
Species : Guinea pig
Method : OECD 406
Result : Does not cause skin sensitisation.

Chronic toxicity

Germ cell mutagenicity

Components:

Methyl 4-hydroxybenzoate:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD 471
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Hamster V79-cells
Metabolic activation: no
Method: OECD 473
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Hamster V79-cells
Metabolic activation: yes
Method: OECD 473
Result: positive

Genotoxicity in vivo : Test Type: Dominant lethale test
Species: Rat (male)
Application Route: Oral
Method: OECD 478
Result: negative

Test Type: Chromosome aberration test in vivo
Species: Rat (male)
Application Route: Oral
Method: OECD 475
Result: negative

Repeated dose toxicity

Components:

Methyl 4-hydroxybenzoate:

Species	:	Rat, male and female
NOAEL	:	250 mg/kg
Application Route	:	Oral
Exposure time	:	28-day
Method	:	OECD 407
Test substance	:	in polyethylene glycol 400
GLP	:	yes

Section 12: Ecological information

Ecotoxicity

Components:

Methyl 4-hydroxybenzoate:

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 59,5 mg/l Exposure time: 96 h Test Type: semi-static test Analytical monitoring: yes Method: OECD 203 GLP: yes
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 11,2 mg/l Exposure time: 48 h Test Type: Immobilization Method: ISO 6341
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 91 mg/l Exposure time: 72 h Test Type: Growth rate Method: ISO 8692
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	EC50 (Daphnia magna (Water flea)): 5,32 mg/l Exposure time: 21 d Test Type: Reproductive toxicity Analytical monitoring: yes Method: OECD 211 NOEC (Daphnia magna (Water flea)): 0,2 mg/l Exposure time: 21 d Test Type: Reproductive toxicity Analytical monitoring: yes Method: OECD 211
Toxicity to microorganisms	:	IC50 (Tetrahymen pyriformis): 125 mg/l Exposure time: 48 h

Persistence and degradability

Components:

Methyl 4-hydroxybenzoate:

Biodegradability	:	aerobic Concentration: 20 mg/l

Biochemical oxygen demand
Result: rapidly biodegradable
Biodegradation: 92,2 %
Exposure time: 28 d
Method: OECD 301F

Stability in water : Test Type: Hydrolysis
Remarks: not hydrolyzed.

Bioaccumulative potential

Components:

Methyl 4-hydroxybenzoate:

Bioaccumulation : Bioconcentration factor (BCF): 6,4
Method: Calculation method
Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : Pow: 95,5 (22 °C)
log Pow: 1,98 (22 °C)
pH: 7,5
Method: OECD 107

Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : No information on ecology is available.
Do not allow to enter surface waters or groundwater.

Components:

Methyl 4-hydroxybenzoate:

Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating (vPvB).

Section 13: Disposal considerations

Disposal methods

Waste from residues : Dispose of as hazardous waste in compliance with local and national regulations.

Contaminated packaging : Contaminated, empty containers are to be treated in the same way as the contents.

Section 14: Transport information

IATA-DGR

Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Section 15: Regulatory information

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

Montreal Protocol (Ozone Depleting Substances)	:	Not applicable
Rotterdam Convention (Prior Informed Consent)	:	Not applicable
Stockholm Convention (Persistent Organic Pollutants)	:	Not applicable

The components of this product are reported in the following inventories:

NZIoC	:	On the inventory, or in compliance with the inventory

Section 16: Other information

Date format	:	dd.mm.yyyy

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No

1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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