

SAFETY DATA SHEET



Ketol

Version 1.0 Revision Date: 24.06.2020 SDS Number: 122000017839 Date of last issue: -
Date of first issue: 24.06.2020

Section 1: Identification

1.1 Product identifier

Ketol

HSNO Approval Number : HSR002521

ACVM number : A000110

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

Use of the Sub-stance/Mixture : Veterinary medicine

1.3 Details of the supplier of the safety data sheet

Company

Elanco New Zealand
Unit A, 123 Ormiston Road
AUCKLAND
NEW ZEALAND
+64-9-272 5420
elanco_sds@elanco.com

1.4 Emergency telephone number

In case of emergency: CHEMTREC International: +1 703-527-3887 (24 hours)
or +64-0800 425 459 (Local toll free)


Section 2: Hazard identification

GHS Classification

Carcinogenicity : 6.7B

Toxic to Reproduction : 6.8B

GHS label elements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H351 Suspected of causing cancer.
H361 Suspected of damaging fertility or the unborn child.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.

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P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P281 Use personal protective equipment as required.

Response:

P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

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)
Cholin chloride	67-48-1	>= 1 -< 10
Cobalt(II) sulphate heptahydrate	10026-24-1	>= 0,1 -< 0,25

Section 4: First-aid measures

General advice : Take off all contaminated clothing immediately.

You should call the National Poisons Centre if you feel that you may have been harmed or irritated by this product. The number is 0800 764 766 (0800 POISON) (24hr emergency service).

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 : If swallowed, seek medical advice immediately and show this container or label.

Most important symptoms and effects, both acute and delayed : No information available.

Notes to physician : No information available.

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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.
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Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propane-1,2-diol	57-55-6	WES-TWA (particulate)	10 mg/m ³	NZ OEL
		WES-TWA (particulate)	10 mg/m ³	NZ OEL
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m ³	NZ OEL
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m ³	NZ OEL
Cobalt(II) sulphate heptahydrate	10026-24-1	TWA	0,02 mg/m ³ (Cobalt)	ACGIH
		TWA	0,02 mg/m ³ (Cobalt)	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Cobalt(II) sulphate heptahydrate	10026-24-1	Cobalt (Cobalt)	Urine	End of shift at end of work-week	15 µg/l	ACGIH BEI
		Cobalt (Cobalt)	Urine	End of shift at end of work-week	15 µg/l	ACGIH BEI

Personal protective equipment

Respiratory protection : Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)

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.

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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
Colour	:	Pink colored
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 (CO ₂)

Section 11: Toxicological information

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate (ATE): > 5.000 mg/kg Method: Calculation method
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Components:

Cholin chloride:

Acute oral toxicity : LD50 (Rat): 3.400 mg/kg
Symptoms: Respiratory disorder, Irritability

Cobalt(II) sulphate heptahydrate:

Acute oral toxicity : LD50 (Rat): 582 mg/kg

Acute inhalation toxicity : TCL0 (Rat): 18 ppm
Exposure time: 6 h

Acute toxicity (other routes of administration) : LD50 (Rat): 320 mg/kg
Application Route: Intramuscular

Skin corrosion/irritation

Components:

Cholin chloride:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Components:

Cholin chloride:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Components:

Cobalt(II) sulphate heptahydrate:

Result : May cause sensitisation by skin contact.
: May cause sensitisation by inhalation.

Chronic toxicity

Germ cell mutagenicity

Components:

Cholin chloride:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Result: negative

Cobalt(II) sulphate heptahydrate:

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Germ cell mutagenicity - Assessment : In vitro tests showed mutagenic effects

Carcinogenicity

Components:

Cobalt(II) sulphate heptahydrate:

Carcinogenicity - Assessment : Positive evidence from human epidemiological studies (inhalation)

Reproductive toxicity

Components:

Cobalt(II) sulphate heptahydrate:

Reproductive toxicity - Assessment : Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.

Further information

Components:

Cholin chloride:

Remarks : Further details are not available.

Section 12: Ecological information

Ecotoxicity

Components:

Cholin chloride:

Toxicity to algae/aquatic plants : IC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Method: DIN 38412

Toxicity to microorganisms : EC50 (Pseudomonas putida): 133 mg/l
Exposure time: 17 h

Ecotoxicology Assessment

Acute aquatic toxicity : slightly hazardous to water

Cobalt(II) sulphate heptahydrate:

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

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Persistence and degradability

Components:

Cholin chloride:

Biodegradability : aerobic
Result: Readily biodegradable.
Biodegradation: 75 %
Exposure time: 5 d

Bioaccumulative potential

Components:

Cholin chloride:

Partition coefficient: n-octanol/water : log Pow: -3,77 (25 °C)
Method: OECD 107

Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : Do not allow to enter surface waters or groundwater.

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

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HSNO Approval Number

HSR002521

HSW Controls

Approved handler certificate required

HSNO tracking not required.

Refer to EPA user guide to the HSNO control regulations for further information.

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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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); EC_x - Concentration associated with x% response; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - 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

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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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