

SAFETY DATA SHEET

Oral-Max



Version 1.0 Revision Date: 13.03.2019 SDS Number: 122000017694 Date of last issue: -
Date of first issue: 13.03.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Oral-Max

HSNO Approval Number : HSR001653

ACVM number : A009642

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

Bayer New Zealand Limited
3 Argus Place
0627 HILLCREST, AUCKLAND, NEW ZEALAND
NEW ZEALAND
Tel.: 0800 652 488
Fax: 0800 229 838
Mail: bhc-md-oeko@bayer.com

1.4 Emergency telephone number


In case of emergency: 0800 734 607 IXOM SH&E Shared services (24hr)

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

6.1: Acute toxicity (Oral) : Category E

GHS label elements

Hazard pictograms : 

Signal word : Warning

Hazard statements : H303 May be harmful if swallowed.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.

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P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Calcium chloride dihydrate	10035-04-8	>= 20 -< 30
Magnesium chloride hexahydrate	7791-18-6	>= 10 -< 20
Methyl 4-hydroxybenzoate	99-76-3	>= 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.
No information available.
- Notes to physician : No information available.

SECTION 5. FIREFIGHTING 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- : Fire may cause evolution of:

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- fighting 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.
No special precautions required.
- 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.

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 (Vapour and particulates)	150 ppm 474 mg/m ³	NZ OEL

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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.
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.
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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : gel
- Colour : colourless
- Odour : weak
- Auto-ignition temperature No data available
非
- Decomposition temperature : No data available
- Explosive properties : No statements available.
- Oxidizing properties : No data available
- Impact sensitivity : No data available
- Minimum ignition energy : No data available
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SECTION 10. STABILITY AND REACTIVITY

- Reactivity : No data available
- Chemical stability : No data available
- Possibility of hazardous reactions : No data available
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Conditions to avoid : No data available

Incompatible materials : Oxidizing agents

Hazardous decomposition products : Carbon monoxide (CO)
Carbon dioxide (CO₂)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate (ATE): 1.617 mg/kg
Method: Calculation method

Components:

Calcium chloride dihydrate:

Acute oral toxicity : LD50 (Rat): 2.301 mg/kg
Method: OECD 401
Remarks: anhydrous substance

Acute dermal toxicity : LD50 (Rat): 2.630 mg/kg
Remarks: anhydrous substance

Magnesium chloride hexahydrate:

Acute oral toxicity : LD50 (Rat): 8.100 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Skin corrosion/irritation

Components:

Calcium chloride dihydrate:

Species: Rabbit
Method: OECD 404
Result: No skin irritation
Remarks: anhydrous substance

Magnesium chloride hexahydrate:

Species: Rabbit
Method: OECD 404
Result: No skin irritation

Methyl 4-hydroxybenzoate:

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

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Serious eye damage/eye irritation

Components:

Calcium chloride dihydrate:

Species: Rabbit
Result: Eye irritation
Method: OECD 405
Remarks: anhydrous substance

Magnesium chloride hexahydrate:

Species: Rabbit
Result: No eye irritation
Method: OECD 405

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:

Calcium chloride dihydrate:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Method: OECD 471
Result: negative
Test substance: anhydrous substance

Magnesium chloride hexahydrate:

Genotoxicity in vitro : Test Type: Bacterial mutagenicity
Result: negative

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

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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

Further information

Components:

Calcium chloride dihydrate:

Remarks: If inhaled
irritations

Magnesium chloride hexahydrate:

Remarks: Ingestion of large quantities:
Nausea
Vomiting
Diarrhoea

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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Calcium chloride dihydrate:

- Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 10.650 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity
Remarks: anhydrous substance
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 144 mg/l
Exposure time: 48 h
Remarks: anhydrous substance
- Toxicity to algae : IC50 (Green algae (Scenedesmos subspicatus)): 3.130 mg/l
Exposure time: 120 h
Remarks: anhydrous substance
- Toxicity to microorganisms : EC50: > 100 mg/l
Remarks: anhydrous substance

Magnesium chloride hexahydrate:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 2.120 mg/l
Exposure time: 96 h
Test substance: anhydrous substance
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1.400 mg/l
Exposure time: 48 h
Test substance: anhydrous substance
- Toxicity to algae : IC50 (Desmodesmus subspicatus (green algae)): 2.200 mg/l
Exposure time: 72 h
Test substance: anhydrous substance
- Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): 36.300 mg/l
Exposure time: 0,5 h
Test substance: anhydrous substance

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 : EC50 (Pseudokirchneriella subcapitata (green algae)): 91 mg/l

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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:

Calcium chloride dihydrate:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

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

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Other adverse effects

Product:

Additional ecological information : 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

International Regulations

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.

National Regulations

SECTION 15. REGULATORY INFORMATION

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

HSNO Approval Number

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HSNO Controls

Approved handler certificate not required.
HSNO tracking not required.
Refer to EPA user guide to the HSNO control regulations for further information.

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

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

SECTION 16. OTHER INFORMATION

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; CPR - Controlled Products Regulations; 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

Date format : dd.mm.yyyy

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

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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