

SAFETY DATA SHEET

Methimazole Spot On



Version 1.0 Revision Date: 01.10.2019 SDS Number: 122000018005 Date of last issue: -
Date of first issue: 01.10.2019

Section 1: Identification

1.1 Product identifier

Methimazole Spot On

HSNO Approval Number : HSR100040

ACVM number : A010271

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: Hazard identification

GHS Classification

Skin irritation : 6.3A

Eye irritation : 6.4A

Toxic to Reproduction : 6.8A

Specific Target Organ Toxicity (Oral) : 6.9A

GHS label elements

Hazard pictograms : The hazard pictograms are two red diamonds. The first diamond contains a black silhouette of a person with a starburst on their chest, representing a health hazard. The second diamond contains a black exclamation mark, representing a general hazard.

Signal word : Danger

Hazard statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.
H360 May damage fertility or the unborn child.

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H372 Causes damage to organs through prolonged or repeated exposure if swallowed.

Precautionary statements : P103 Read label before use.

Prevention:

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and 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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P314 Get medical advice/ attention if you feel unwell.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/container to an approved facility in accordance with local, regional, national and international regulations.

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)
Polyethyleneglycol	25322-68-3	>= 20 -< 30
Thiamazole	60-56-0	>= 1 -< 10
1-Methyl-2-pyrrolidone	872-50-4	>= 1 -< 10
Oleic acid	112-80-1	>= 1 -< 10

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)

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- 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.

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

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Conditions for safe storage : must be observed!
: 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
1-Methyl-2-pyrrolidone	872-50-4	WES-STEL	75 ppm 309 mg/m ³	NZ OEL
	Further information: Skin absorption			
		WES-TWA	25 ppm 103 mg/m ³	NZ OEL
	Further information: Skin absorption			

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
1-Methyl-2-pyrrolidone	872-50-4	5-Hydroxy-N-methyl-2-pyrrolidone	Urine	End of shift (As soon as possible after exposure ceases)	100 mg/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.
For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.

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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 : paste
Colour : colourless to yellow
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

Acute toxicity

Product:

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

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

Components:

Polyethyleneglycol:

Acute oral toxicity : LD50 (Rat, female): > 2.000 mg/kg
Method: OECD 423
GLP: yes
Remarks: No mortality with maximum tested dose.

Acute dermal toxicity : LD50 (Rat, male and female): > 2.000 mg/kg
Method: OECD 402

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GLP: yes
Assessment: The available study results do not lead to a GHS classification
Remarks: No mortality observed at this dose.

1-Methyl-2-pyrrolidone:

- Acute oral toxicity : LD50 (Rat): 4.150 mg/kg
Method: OECD 401
- Acute inhalation toxicity : LC50 (Rat): > 5,1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist/aerosol
Method: OECD 403
Assessment: No adverse effect has been observed in acute toxicity tests.
- Acute dermal toxicity : LD50 (Rat): > 5.000 mg/kg
Method: OECD 402
Assessment: No adverse effect has been observed in acute toxicity tests.

Oleic acid:

- Acute oral toxicity : LD50 (Rat, male and female): > 2.000 mg/kg
Method: OECD 401
Test substance: Data on a comparable substance
Assessment: No adverse effect has been observed in acute toxicity tests.
- Acute inhalation toxicity : (Rat): > 5,7 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist/aerosol
Method: OECD 436
Test substance: Data on a comparable substance
GLP: yes
Assessment: No adverse effect has been observed in acute toxicity tests.
- Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD 402
Test substance: Data on a comparable substance
GLP: yes
Assessment: No adverse effect has been observed in acute toxicity tests.

Skin corrosion/irritation

Components:

Polyethyleneglycol:

- Species : Rabbit
Exposure time : 4 h
Method : OECD 404
Result : No skin irritation

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GLP : yes

1-Methyl-2-pyrrolidone:

Species : Rabbit
Result : Skin irritation

Oleic acid:

Species : Rabbit
Exposure time : 4 h
Method : OECD 404
Result : No skin irritation
GLP : yes
Test substance : Data on a comparable substance

Serious eye damage/eye irritation

Components:

Polyethyleneglycol:

Species : Rabbit
Result : No eye irritation
Exposure time : 24 h
Assessment : The available study results do not lead to a GHS classification
Method : OECD 405
GLP : yes

1-Methyl-2-pyrrolidone:

Species : Rabbit
Result : Irritating to eyes.

Oleic acid:

Species : Rabbit
Result : No eye irritation
Method : OECD 405
GLP : yes
Test substance : Data on a comparable substance

Respiratory or skin sensitisation

Components:

Polyethyleneglycol:

Test Type : Maximisation Test
Exposure routes : Intradermal + epicutan
Species : Guinea pig
Assessment : The available study results do not lead to a GHS classification
Result : Did not cause sensitisation on laboratory animals.
Remarks : Information taken from reference works and the literature.

1-Methyl-2-pyrrolidone:

Test Type : Skin sensitisation

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Species : Mouse
Method : OECD 429
Result : Does not cause skin sensitisation.
Test substance : Data on a comparable substance

: Skin sensitisation
: Human experience
: Patch Test
: Does not cause skin sensitisation.

Oleic acid:

Test Type : Skin sensitisation
Species : Mouse
Method : OECD 429
Result : Does not cause skin sensitisation.
Test substance : Data on a comparable substance

Chronic toxicity

Germ cell mutagenicity

Components:

Polyethyleneglycol:

Genotoxicity in vitro : Test Type: reverse mutation assay
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD 471
Result: negative
GLP: No information available.
Remarks: Information taken from reference works and the literature.

Test Type: In vitro gene mutation study in mammalian cells
Test system: Hamster ovary-cells
Metabolic activation: with and without metabolic activation
Method: OECD 476
Result: negative
GLP: yes

1-Methyl-2-pyrrolidone:

Genotoxicity in vitro : Test Type: Bacterial mutagenicity
Result: No indication of mutagenic effects.

Genotoxicity in vivo : Remarks: In vivo tests did not show mutagenic effects

Oleic acid:

Genotoxicity in vitro : Test Type: In vitro gene mutation study in mammalian cells
Test system: Hamster V79-cells
Metabolic activation: with and without metabolic activation
Method: OECD 476
Result: negative
GLP: yes

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Test Type: Chromosome aberration test in vitro
Test system: Hamster V79-cells
Metabolic activation: with and without metabolic activation
Method: OECD 473
Result: negative
GLP: yes

Carcinogenicity

Components:

1-Methyl-2-pyrrolidone:

Result : Animal testing did not show any carcinogenic effects.

Reproductive toxicity

Components:

1-Methyl-2-pyrrolidone:

Effects on fertility : Species: Rat
Application Route: Oral
General Toxicity - Parent: LOAEL: 500 mg/kg body weight
Fertility: NOAEL: 350 mg/kg body weight
Method: OECD 416
Result: Animal studies have produced evidence a fertility-reducing effect.

Effects on foetal development : Species: Rat
Application Route: Oral
Frequency of Treatment: 1 daily
Developmental Toxicity: NOAEL: 160 mg/kg body weight
Method: OECD 416
Result: May damage the unborn child.

STOT - single exposure

Components:

1-Methyl-2-pyrrolidone:

Assessment : May cause respiratory irritation.

Repeated dose toxicity

Components:

Polyethyleneglycol:

Species : Rat, male and female
NOEL : 8000 mg/kg
Application Route : Oral
Exposure time : 90-day
Number of exposures : Continuous exposure via feed.
GLP : No information available.
Remarks : Information taken from reference works and the literature.

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Species : Rat, male and female
LOAEL : 16000 mg/kg
Application Route : Oral
Exposure time : 90-day
Number of exposures : Continuous exposure via feed.
GLP : No information available.
Remarks : Information taken from reference works and the literature.

Species : Rat, male and female
NOEC : 1000 mg/kg
Application Route : inhalation (dust/mist/fume)
Test atmosphere : dust/mist/aerosol
Exposure time : 13 Weeks
Number of exposures : 6 hours a day, 5 days per week
GLP : No information available.
Remarks : Information taken from reference works and the literature.

Oleic acid:

Species : Rat, male
NOAEL : 1.000 mg/kg
Application Route : Oral
Exposure time : 6 weeks
Number of exposures : Once daily
Method : OECD 422
Test substance : Data on a comparable substance
GLP : yes

Species : Rat, female
NOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 6 weeks
Number of exposures : Once daily
Method : OECD 422
Test substance : Data on a comparable substance
GLP : yes

Further information

Components:

1-Methyl-2-pyrrolidone:

Remarks : Dermal absorption possible

Section 12: Ecological information

Ecotoxicity

Components:

Polyethyleneglycol:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 g/l
Exposure time: 96 h

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Test Type: Acute Fish toxicity
Analytical monitoring: no
Method: OECD 203
GLP: no
Remarks: The available study results do not lead to a GHS classification

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: Immobilization
Method: OECD 202
GLP: no
Remarks: Nominal concentration
The available study results do not lead to a GHS classification

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 96 h
Test Type: Growth rate
Analytical monitoring: no
Method: OECD 201
GLP: no
Remarks: Nominal concentration
The available study results do not lead to a GHS classification

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 17.475,27 mg/l
Exposure time: 21 d
Test Type: Immobilization
Method: prediction model

Toxicity to microorganisms : EC50: > 1.000 mg/l
Method: OECD 209
Remarks: The available study results do not lead to a GHS classification

EC50 (Chilomonas paramecium): 2.774 mg/l
Exposure time: 48 h
Test Type: Cell multiplication inhibition test
Analytical monitoring: no
GLP: no
Remarks: Information taken from reference works and the literature.

1-Methyl-2-pyrrolidone:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 1.000 mg/l
Exposure time: 24 h
Method: DIN 38412

NOEC (Daphnia magna (Water flea)): 1.000 mg/l
Exposure time: 24 h
Method: DIN 38412

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Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC20: > 600 mg/l
Exposure time: 0,5 h
Method: OECD 209

Oleic acid:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Test substance: Data on a comparable substance
Method: OECD 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: Immobilization
Analytical monitoring: yes
Test substance: Data on a comparable substance
Method: OECD 202
GLP: yes

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: Growth rate
Analytical monitoring: yes
Test substance: Data on a comparable substance
Method: OECD 201
GLP: yes

Toxicity to microorganisms : EC50 (Activated sludge micro-organism): > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Analytical monitoring: no
Test substance: Data on a comparable substance
Method: OECD 209
GLP: yes

Persistence and degradability

Components:

Polyethyleneglycol:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: < 20 %
Method: OECD 302B

aerobic
Inoculum: Microbial inoculum
Concentration: 4 mg/l
Result: Readily biodegradable.

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Biodegradation: 74,85 %
Testing period: 7 d
Kinetic:
7 d: 19,6 %
14 d: 37,12 %
21 d: 41,91 %
28 d: 74,85 %
Method: OECD 301 D
GLP: no

Stability in water : Test Type: Hydrolysis
Degradation half life (DT50): 15 d
Method: prediction model

1-Methyl-2-pyrrolidone:

Biodegradability : Result: Readily biodegradable.
Biodegradation: > 90 %
Method: OECD 301E

Biochemical Oxygen Demand (BOD) : 2 mg/g
Incubation time: 5 d

Chemical Oxygen Demand (COD) : 1.600 mg/l
ThOD : 1.939 mg/g

Oleic acid:

Biodegradability : aerobic
Concentration: 100 mg/l
Biochemical oxygen demand
Result: rapidly biodegradable
Biodegradation: 75,3 %
Exposure time: 28 d
Method: OECD 301 C
Test substance: Data on a comparable substance

Stability in water : Degradation half life: 20,4 a (25 °C) pH: 7
Method: EPA 161-1

Bioaccumulative potential

Components:

Polyethyleneglycol:

Bioaccumulation : Species: Fish
Bioconcentration factor (BCF): 3.162
Temperature: 25 °C
Method: prediction model
Remarks: Does not bioaccumulate.

1-Methyl-2-pyrrolidone:

Partition coefficient: n- : log Pow: -0,46

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octanol/water

Oleic acid:

Bioaccumulation : Species: *Lepomis macrochirus* (Bluegill sunfish)
Bioconcentration factor (BCF): < 17
Exposure time: 28 d
Test substance: Data on a comparable substance

Partition coefficient: n-octanol/water : log Pow: 16,15

Mobility in soil

No data available

Other adverse effects

Product:

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

Components:

Oleic acid:

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

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