

SAFETY DATA SHEET

Advocate® Spot On



Version 2.0 Revision Date: 16.09.2019 SDS Number: 122000001555 Date of last issue: 03.09.2019
Date of first issue: 24.07.2017

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

Product identifier

Advocate® Spot On
Imidacloprid 10% / Moxidectin 0,5 - 2,5% Spot On

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

Use of the Sub-stance/Mixture : veterinary medicine
unfinished

Details of the supplier of the safety data sheet

Company

Bayer Australia Limited
875 Pacific Highway
PYMBLE 2073
AUSTRALIA
Tel.: +61 29391 6000
Mail: sdshealthcare.au@bayer.com

Emergency telephone number

In case of emergency: 1800 033 111

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 4
Acute toxicity (Inhalation) : Category 4
Serious eye damage/eye irritation : Category 2A

GHS label elements

Hazard pictograms :



Signal word : Warning
Hazard statements : H302 + H332 Harmful if swallowed or if inhaled.
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.
Response:

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P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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)
Benzyl alcohol	100-51-6	>= 60 - <= 100
Propylene carbonate	108-32-7	>= 10 - < 30
Imidacloprid	138261-41-3	< 10
Moxidectin	113507-06-5	< 10

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 : 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. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
- Unsuitable extinguishing : High volume water jet

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media

- Specific hazards during fire-fighting : Fire may cause evolution of:
Hydrogen cyanide (hydrocyanic acid)
Hydrogen chloride gas
Nitrogen oxides (NO_x)
Carbon oxides
- 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

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Imidacloprid	138261-41-3	SUP	0.7 mg/m ³	
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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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : yellow, brownish, clear

Odour : weak, characteristic

Flash point : > 100 °C

Density : 1.098 g/cm³ (20 °C)

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

SECTION 10. STABILITY AND REACTIVITY

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Reactivity : No data available

Chemical stability : No data available

Possibility of hazardous reactions : Exothermic polycondensation, accompanied by setting-free of water, may occur in the presence of acids and dissolved iron, zinc or aluminium.

Conditions to avoid : Do not allow product to come in contact with:
Heat

Incompatible materials : Oxidizing agents

Hazardous decomposition products : Hydrogen cyanide (hydrocyanic acid)
Hydrogen chloride gas
Nitrogen oxides (NO_x)
Carbon oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate (ATE): 1,319 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate (ATE): 14.7 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Components:

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat, male): 1,620 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Propylene carbonate:

Acute oral toxicity : LD50 (Rat): 32,100 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity : Exposure time: 8 h
Assessment: No adverse effect has been observed in acute toxicity tests.
Remarks: An LC50/inhalation/8h/rat could not be determined because no mortality of rats was observed at the maximum achievable concentration.

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Acute dermal toxicity : LD50 (Rabbit): > 20,000 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Imidacloprid:

Acute oral toxicity : LD50 (Rat): 424 mg/kg
Assessment: The component/mixture is toxic after single ingestion.

Acute inhalation toxicity : LC50 (Rat): > 5.323 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist/aerosol
Method: OECD 403
Assessment: The component/mixture is minimally toxic after short term inhalation.

Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Moxidectin:

Acute oral toxicity : LD50 (Rat): 106 mg/kg
Assessment: The component/mixture is toxic after single ingestion.

Acute inhalation toxicity : LC50 (Rat): 4.1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist/aerosol
Method: Calculation method
Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The component/mixture is minimally toxic after single contact with skin.

Acute toxicity (other routes of administration) : LD50 (Rat): 394 mg/kg
Application Route: Intraperitoneal

LD50 (Rat): > 640 mg/kg
Application Route: Subcutaneous

Skin corrosion/irritation

Components:

Benzyl alcohol:

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

Propylene carbonate:

Species: Rabbit

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Method: OECD 404
Result: No skin irritation

Imidacloprid:

Species: Rabbit
Result: No skin irritation

Moxidectin:

Result: Moderate skin irritation

Serious eye damage/eye irritation

Components:

Benzyl alcohol:

Species: Rabbit
Result: Irritation to eyes, reversing within 7 days
Method: OECD 405

Propylene carbonate:

Species: Rabbit
Result: Eye irritation
Method: OECD 405

Imidacloprid:

Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Components:

Benzyl alcohol:

Species: Guinea pig
Method: Magnusson and Kligmann maximization test
Result: Did not cause sensitisation on laboratory animals.

Propylene carbonate:

Result: Does not cause skin sensitisation.

Imidacloprid:

Test Type: Skin sensitisation
Species: Guinea pig
Method: Magnusson and Kligmann maximization test
Result: Did not cause sensitisation on laboratory animals.



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Chronic toxicity

Germ cell mutagenicity

Components:

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Genotoxicity in vivo : Result: No indication of mutagenic effects.

Propylene carbonate:

Genotoxicity in vivo : Result: No indication of mutagenic effects.

Imidacloprid:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

: Remarks: In vitro tests did not show mutagenic effects

Genotoxicity in vivo : Result: No indication of mutagenic effects., No evidence of a genotoxic effect.

Reproductive toxicity

Components:

Moxidectin:

Reproductive toxicity - Assessment : No toxicity to reproduction

STOT - single exposure

Components:

Benzyl alcohol:

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Components:

Benzyl alcohol:

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Imidacloprid:

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

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Repeated dose toxicity

Components:

Benzyl alcohol:

Species: Rat
NOAEL: 400 mg/kg
Exposure time: 90-day

Further information

Components:

Benzyl alcohol:

Remarks: Dermal absorption possible

Remarks: If inhaled:
irritations
Shortness of breath
Cough

Remarks: If swallowed
Vomiting
Nausea

Irritation of mucous membranes in the mouth, throat, gullet and gastro-intestinal tract after swallowing.

Remarks: Systemic toxicity
Headache
Nausea
CNS disorders
Ataxia (uncontrolled movements)
Unconsciousness
cessation of breathing

Imidacloprid:

Pharmaceutic effects
Remarks: Insecticide

Moxidectin:

Pharmaceutic effects
Remarks: Anthelmintics
Antiparasitic agent

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

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

Components:

Benzyl alcohol:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 10 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 71.4 mg/l
Exposure time: 0.5 h

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic to aquatic life.

Propylene carbonate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): ca. 5,300 mg/l
Exposure time: 96 h
Test Type: static test
Method: DIN 38412

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h
Test Type: static test

Toxicity to algae : (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h
Test Type: static test
Method: DIN 38412

Toxicity to bacteria : EC20 (Activated sludge micro-organism): > 800 mg/l
Exposure time: 0.5 h
Method: ISO 8192

Ecotoxicology Assessment

Acute aquatic toxicity : slightly hazardous to water

Imidacloprid:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 237 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 85 mg/l
Exposure time: 48 h

Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h

EC50 (Desmodesmus subspicatus (green algae)): > 10 mg/l
Exposure time: 72 h

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Toxicity to bacteria : EC50 (Activated sludge micro-organism): > 10,000 mg/l
Method: OECD 209

Moxidectin:

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

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

Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability : Result: rapidly biodegradable
Biodegradation: 92 - 96 %
Exposure time: 28 d
Method: OECD 301 C

Propylene carbonate:

Biodegradability : Result: rapidly biodegradable

BOD/ThOD : 86 %

Dissolved organic carbon (DOC) : 90 - 100 %
Method: ISO 7827
GLP: %

Imidacloprid:

Stability in water : Degradation half life: > 1 a (25 °C) pH: 4
Hydrolysis: at25 °C

Degradation half life: > 1 a (25 °C) pH: 7
Hydrolysis: at25 °C

Degradation half life: ca. 1 h (25 °C) pH: 9
Hydrolysis: at25 °C

Moxidectin:

Stability in water : Degradation half life: 180 d

Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

Propylene carbonate:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water,

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accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -0.48 (25 °C)

Imidacloprid:

Bioaccumulation : Remarks: Low potential for bioaccumulation

Partition coefficient: n-octanol/water : log Pow: 0.57 (21 °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.

Components:

Propylene carbonate:

Adsorbed organic bound halogens (AOX) : Remarks: Product does not contain any organic halogens.

Imidacloprid:

Adsorbed organic bound halogens (AOX) : Remarks: The product contains organic halogens.

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

UN/ID No. : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (MOXIDECTIN)
Class : 9
Packing group : III
Labels : 9

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Packing instruction (cargo aircraft) : 964

Packing instruction (passenger aircraft) : 964

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (MOXIDECTIN)

Class : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

ADG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (MOXIDECTIN)

Class : 9

Packing group : III

Labels : 9

Hazchem Code : •3Z

SECTION 15. REGULATORY INFORMATION

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

No statements available.

Standard for the Uniform Scheduling of Medicines and Poisons : **Schedule 5: Poisons to be labeled: Caution**

Standard for the Uniform Scheduling of Medicines and Poisons : **Schedule 6: Poisons to be labeled: Poison**

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

AICS : Not in compliance with the inventory

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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

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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