

SAFETY DATA SHEET

Advantix® Spot on Defense Care Flea/Tick for Dogs



Version 1.0 Revision Date: 03.09.2019 SDS Number: 122000002469 Date of last issue: -
Date of first issue: 03.09.2019

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

Product identifier

Advantix® Spot on Defense Care Flea/Tick for Dogs
IMI 10% Permethrin 50% SO
Imidacloprid 10% Permethrin 50% SO
Fortreon
TICKGARD
BAYVANTIC VET DOG
Kiltix

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

Use of the Substance/Mixture : veterinary medicine

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

Flammable liquids : Category 4
Acute toxicity (Oral) : Category 4
Serious eye damage/eye irritation : Category 2A
Reproductive toxicity : Category 1B
Specific target organ toxicity - single exposure : Category 3 (Respiratory system)

GHS label elements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H227 Combustible liquid.

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H302 Harmful if swallowed.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H360 May damage fertility or the unborn child.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P210 Keep away from heat/sparks/open flames/hot surfaces.
No smoking.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P281 Use personal protective equipment as required.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

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)
Permethrin	52645-53-1	>= 30 - < 60
1-Methyl-2-pyrrolidone	872-50-4	>= 30 - < 60
Imidacloprid	138261-41-3	< 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 media : High volume water jet

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Specific hazards during fire-fighting : Hydrogen chloride gas
 Hydrogen cyanide (hydrocyanic acid)
 Nitrogen oxides (NOx)
 Chlorine gas
 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
Permethrin	52645-53-1	SUP	10 mg/m ³	
1-Methyl-2-pyrrolidone	872-50-4	STEL	75 ppm 309 mg/m ³	AU OEL
Further information: Skin absorption				
		TWA	25 ppm 103 mg/m ³	AU OEL
Further information: Skin absorption				

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Imidacloprid	138261-41-3	SUP	0.7 mg/m ³
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Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam-pling time	Permissible concentra-tion	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.
 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 : tan
 Odour : very faint, aromatic
 pH : 3 - 5
 Boiling point/boiling range : 199 °C
 Method: OECD 102
 Flash point : 92.8 °C
 Density : 1.14 g/cm³ (20 °C)
 Auto-ignition temperature : No data available
 Decomposition temperature : No data available
 Explosive properties : No data available

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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 : Do not allow product to come in contact with:
Heat
Incompatible materials : Oxidizing agents
Bases
Hazardous decomposition products : Hydrogen chloride gas
Hydrogen cyanide (hydrocyanic acid)
Nitrogen oxides (NO_x)
Chlorine gas
Carbon oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : LD50 (Rat, female): 1,660 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

Acute inhalation toxicity : LC50 (Rat): Test atmosphere: vapour
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: An LC50/inhalation/4h/rat could not be determined because no mortality of rats was observed at the maximum achievable concentration.

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

Components:

Permethrin:

Acute oral toxicity : LD50 (Rat): 430 mg/kg
Assessment: The component/mixture is toxic after single ingestion.

Acute inhalation toxicity : LC50 (Rat): 2.3 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist/aerosol
Assessment: The component/mixture is moderately toxic after short term inhalation.

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Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
LD50 (Rat): > 2,500 mg/kg
Assessment: The component/mixture is minimally toxic after single contact with skin.

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.

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.

Skin corrosion/irritation

Product:

Species: Rabbit
Exposure time: 4 h
Result: No skin irritation
GLP: yes

Components:

Permethrin:

Species: Rabbit
Result: No skin irritation

1-Methyl-2-pyrrolidone:

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Species: Rabbit
Result: Skin irritation

Imidacloprid:

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Product:

Species: Rabbit
Result: Moderate eye irritation
Exposure time: 24 h
GLP: yes

Components:

Permethrin:

Species: Rabbit
Result: Mild eye irritation

1-Methyl-2-pyrrolidone:

Species: Rabbit
Result: Irritating to eyes.

Imidacloprid:

Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Product:

Test Type: Skin sensitisation
Species: Guinea pig
Method: Buehler Test
Result: Did not cause sensitisation on laboratory animals.

Components:

Permethrin:

Result: May cause sensitisation by skin contact.

1-Methyl-2-pyrrolidone:

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

Test Type: Skin sensitisation
Species: Human experience

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Method: Patch Test
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.

Chronic toxicity

Germ cell mutagenicity

Components:

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

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.

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

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Method: OECD 416
Result: May damage the unborn child.

STOT - single exposure

Components:

1-Methyl-2-pyrrolidone:

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Components:

Imidacloprid:

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

Further information

Components:

Permethrin:

Pharmaceutic effects
Remarks: Insecticide

Remarks: Cutaneous sensations may occur, such as burning or stinging on the face and mucosae. However, these sensations cause no lesions and are of a transitory nature (max. 24 hours).

1-Methyl-2-pyrrolidone:

Remarks: Dermal absorption possible

Imidacloprid:

Pharmaceutic effects
Remarks: Insecticide

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Permethrin:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.00017 mg/l
Exposure time: 48 h

Toxicity to algae : EC50: 0.5 mg/l
Exposure time: 72 h

1-Methyl-2-pyrrolidone:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l

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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

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

Toxicity to bacteria : EC20: > 600 mg/l
Exposure time: 0.5 h
Method: OECD 209

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

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

Persistence and degradability

Components:

Permethrin:

Biodegradability : Result: Not rapidly biodegradable
Biodegradation: 0 %
Testing period: 7 d
Exposure time: 28 d
Kinetic:
7 d: 0 %
14 d: 0 %
21 d: 0 %
28 d: 0 %

1-Methyl-2-pyrrolidone:

Biodegradability : Result: Readily biodegradable.
Biodegradation: > 90 %

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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

Imidacloprid:

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

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

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

Bioaccumulative potential

Components:

Permethrin:

Partition coefficient: n-octanol/water : log Pow: 5.95

1-Methyl-2-pyrrolidone:

Partition coefficient: n-octanol/water : log Pow: -0.46

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:

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

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Contaminated packaging : national regulations.
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. (PERMETHRIN, IMIDACLOPRID, N-METHYLPYRROLIDONE)
Class : 9
Packing group : III
Labels : 9
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. (PERMETHRIN, IMIDACLOPRID, N-METHYLPYRROLIDONE)
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. (PERMETHRIN, IMIDACLOPRID, N-METHYLPYRROLIDONE)
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

Standard for the Uniform Scheduling of Medicines and Poisons : Schedule 5

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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

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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