

SAFETY DATA SHEET

Advantage® Topical Solution



Version 1.0 Revision Date: 03.09.2019 SDS Number: 122000001165 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

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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:

P304 + P340 + P312 IF INHALED: Remove victim to fresh air

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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

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

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

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 exter-

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nal 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, brown, clear
Odour	:	mild
pH	:	ca. 6.4 (20 °C) Concentration: 10 g/l
Pour point	:	-28 - -25 °C
Flash point	:	98.9 °C
Density	:	1.098 g/cm ³ (20 °C)
Auto-ignition temperature	:	415 °C Method: DIN 51794
Decomposition temperature	:	No data available
Flow time	:	28.7 s (20 °C) Cross section: 3 mm Method: ISO 2431
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	:	Hydrogen cyanide (hydrocyanic acid) Hydrogen chloride gas Nitrogen oxides (NO _x) Carbon oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : LD50 (Rat, female): 1,742 mg/kg

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- Acute inhalation toxicity : LC50 (Rat): > 2.415 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist/aerosol
Assessment: Harmful if inhaled.
- Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Assessment: May be harmful in contact with skin.

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: The substance or mixture has no acute inhalation toxicity
Remarks: An LC50/inhalation/8h/rat could not be determined because no mortality of rats was observed at the maximum achievable concentration.
- 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.

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Skin corrosion/irritation

Product:

Species: Rabbit
Result: Mild skin irritation

Components:

Benzyl alcohol:

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

Propylene carbonate:

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

Imidacloprid:

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Product:

Species: Rabbit
Result: 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

Product:

Test Type: Skin sensitisation
Species: Pig
Result: Did not cause sensitisation on laboratory animals.

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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.

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.

STOT - single exposure

Components:

Benzyl alcohol:

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

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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.

Repeated dose toxicity

Components:

Benzyl alcohol:

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

Further information

Product:

Pharmaceutical effects
Remarks: Antiparasitic agent

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:

Pharmaceutical effects

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Remarks: Insecticide

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Toxicity to fish : (Lepomis macrochirus (Bluegill sunfish)): > 105 ppm

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

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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:

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

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, accumulation in organisms is not expected.

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

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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. (IMIDACLOPRID)
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. (IMIDACLOPRID)
Class : 9

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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

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