

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

1.1 Product identifier

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HSNO Approval Number : HSR001760

ACVM number : A009546

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

3.1: Flammable Liquids : Category D

6.1: Acute toxicity (Oral) : Category E

6.4: Eye irritation : Category A

6.8: Toxic to Reproduction : Category B

6.9: Specific Target Organ Toxicity (Oral) : Category B (Pancreas, Liver, Kidney, Glucose Metabolism, Central nervous system)

9.1: Aquatic toxicity (Acute or Chronic) : Category A

GHS label elements

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

Hazard pictograms :

Signal word : Warning

Hazard statements : H227 Combustible liquid.
H303 May be harmful if swallowed.
H319 Causes serious eye irritation.
H361 Suspected of damaging fertility or the unborn child.
H373 May cause damage to organs (Pancreas, Liver, Kidney, Glucose Metabolism, Central nervous system) through prolonged or repeated exposure if swallowed.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ 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)
2,2-Dimethyl-1,3-dioxolan-4-ylmethanol	100-79-8	>= 70 -< 90
Praziquantel	55268-74-1	>= 1 -< 10
Lactic acid	50-21-5	>= 1 -< 10
Emodepside	155030-63-0	>= 1 -< 2,5
2-tert-Butyl-4-methoxyphenol	121-00-6	>= 0,1 -< 1

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.

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

- 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-fighting : Fire may cause evolution of:
Nitrogen oxides (NO_x)
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.
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SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire : No special protective measures against fire required.
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SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

fire and explosion

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
Emodepside	155030-63-0	Bayer OES	0,03 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 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

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

Colour : colourless

Odour : weak

Boiling point/boiling range : ca. 190 °C

Flash point : 80 °C

Density : 1,081 g/cm³ (20 °C)
Method: DIN 51757

Auto-ignition temperature : No data available

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

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

Hazardous decomposition products : Nitrogen oxides (NO_x)
Carbon monoxide (CO)
Carbon dioxide (CO₂)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate (ATE): 4.899 mg/kg
Method: Calculation method

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

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

Components:

2,2-Dimethyl-1,3-dioxolan-4-ylmethanol:

Acute oral toxicity : LD50 (Rat): 7.000 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute toxicity (other routes of administration) : LD50 (Rat): 3.000 mg/kg
Application Route: Intraperitoneal

Praziquantel:

Acute oral toxicity : LD50 (Rat): 2.840 mg/kg

Lactic acid:

Acute oral toxicity : LD50 (Rat): 3.543 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Emodepside:

Acute oral toxicity : LD50 (Rat): > 500 - < 1.000 mg/kg
Method: OECD 423
Assessment: The component/mixture is moderately toxic after single ingestion.

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD 402
Assessment: The component/mixture is minimally toxic after single contact with skin.

2-tert-Butyl-4-methoxyphenol:

Acute oral toxicity : LD50 (Rat): 880 mg/kg

Skin corrosion/irritation

Components:

2,2-Dimethyl-1,3-dioxolan-4-ylmethanol:

Species: Rabbit
Result: No skin irritation

Lactic acid:

Result: irritating

Emodepside:

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

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

Serious eye damage/eye irritation

Components:

Praziquantel:

Result: May irritate eyes.

Lactic acid:

Result: Risk of serious damage to eyes.

Emodepside:

Species: Rabbit

Result: No eye irritation

Method: OECD 405

Respiratory or skin sensitisation

Components:

2,2-Dimethyl-1,3-dioxolan-4-ylmethanol:

Assessment: An acute toxic effect is not expected.

Lactic acid:

Result: Does not cause skin sensitisation.

Emodepside:

Species: Guinea pig

Method: OECD 406

Result: Does not cause skin sensitisation.

Chronic toxicity

Germ cell mutagenicity

Components:

2,2-Dimethyl-1,3-dioxolan-4-ylmethanol:

Genotoxicity in vitro : Test Type: Ames test
Result: No indication of mutagenic effects.

Test Type: Chromosome aberration test in vitro
Result: negative

Praziquantel:

Genotoxicity in vitro : Test Type: Ames test
Result: No indication of mutagenic effects.

Lactic acid:

Genotoxicity in vitro : Remarks: Tests with bacteria and mammalian cells showed
no evidence of genotoxic effects.

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

Emodepside:

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

Test Type: V79-HPRT Forward Mutation Assay
Test system: Hamster V79-cells
Method: OECD 476
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Hamster V79-cells
Method: OECD 473
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Intraperitoneal
Method: OECD 474
Result: negative

2-tert-Butyl-4-methoxyphenol:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Result: negative

Carcinogenicity

Components:

Praziquantel:

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

Reproductive toxicity

Components:

Praziquantel:

Reproductive toxicity - Assessment : No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.

STOT - single exposure

Components:

Praziquantel:

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

2-tert-Butyl-4-methoxyphenol:

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

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

exposure.

STOT - repeated exposure

Components:

Praziquantel:

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

Emodepside:

Exposure routes: Ingestion

Target Organs: Pancreas, Liver, Kidney, Glucose Metabolism, Central nervous system

Assessment: Causes damage to the nervous system through prolonged or repeated exposure.

2-tert-Butyl-4-methoxyphenol:

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

Repeated dose toxicity

Components:

2,2-Dimethyl-1,3-dioxolan-4-ylmethanol:

Repeated dose toxicity - : An acute toxic effect is not expected.
Assessment

Emodepside:

Species: Rat, male

LOAEL: 4,2 mg/kg, 50 ppm

Application Route: Oral

Exposure time: 4 weeks

Method: OECD 407

Species: Mouse, female

NOAEL: 16,8 mg/kg, 50 ppm

LOAEL: 79,1 mg/kg, 250 ppm

Application Route: Oral

Exposure time: 13 Weeks

Method: OECD 408

Target Organs: pancreatic islet, Liver, Kidney, Glucose Metabolism, Central nervous system

Further information

Components:

Praziquantel:

Pharmaceutic effects

Remarks: Anthelmintics

Remarks: Ingestion of large quantities:

Drowsiness

Difficulty in breathing

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

Ataxia (uncontrolled movements)
Tiredness

Emodepside:

Pharmaceutic effects
Remarks: Antiparasitic agent

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2,2-Dimethyl-1,3-dioxolan-4-ylmethanol:

Ecotoxicology Assessment

Acute aquatic toxicity : slightly water endangering

Praziquantel:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): 35 mg/l
Exposure time: 48 h

Toxicity to algae : EbC50 (Desmodesmus subspicatus (green algae)): 140 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test

ErC50 (Desmodesmus subspicatus (green algae)): 77 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test

NOEbC (Desmodesmus subspicatus (green algae)): 25 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test

NOErC (Desmodesmus subspicatus (green algae)): 25 mg/l
Exposure time: 72 h
Test Type: Cell multiplication inhibition test

Toxicity to microorganisms : EC50 (activated sludge micro-organism): > 1.000 mg/l
Exposure time: 3 h
Method: OECD 209

Ecotoxicology Assessment

Acute aquatic toxicity : Harmful to aquatic life.

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

Lactic acid:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 240 mg/l
Exposure time: 48 h

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

Ecotoxicology Assessment

Acute aquatic toxicity : slightly water endangering

Emodepside:

Toxicity to fish : LC0: > 0,01 mg/l
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,0021 mg/l
Exposure time: 48 h

Toxicity to algae : EC0: 0,01 mg/l
Exposure time:
Remarks: No toxicity at the limit of solubility

M-Factor (Acute aquatic toxicity) : 100

Toxicity to microorganisms : EC50 (adapted and activated sludge micro-organism): > 10.000 mg/l

Toxicity to soil dwelling organisms : LC50: > 1.000 mg/kg
Exposure time: 14 d

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:

Praziquantel:

Biodegradability : Result: Not rapidly biodegradable
Biodegradation: 0 %

Chemical Oxygen Demand (COD) : 2.340 mg/g
Method: DIN 38414

Lactic acid:

Biochemical Oxygen Demand (BOD) : 0,45 mg/g
Incubation time: 5 d

0,60 mg/g
Incubation time: 20 d

Chemical Oxygen Demand (COD) : 0,90 mg/g

Emodepside:

Biodegradability : Result: Not rapidly biodegradable

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

Bioaccumulative potential

Components:

Praziquantel:

Partition coefficient: n-octanol/water : log Pow: 2,012

Lactic acid:

Partition coefficient: n-octanol/water : log Pow: -0,62

Emodepside:

Partition coefficient: n-octanol/water : log Pow: 4,9
pH: 7

2-tert-Butyl-4-methoxyphenol:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: 3,5
Method: Calculation method

Mobility in soil

No data available

Other adverse effects

Product:

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

Components:

Lactic acid:

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

SAFETY DATA SHEET

Profender



Version 1.0 Revision Date: 05.03.2019 SDS Number: 122000001666 Date of last issue: -
Date of first issue: 05.03.2019

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (EMODEPSIDE)
Class : 9
Packing group : III
Labels : 9
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (EMODEPSIDE)
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

SECTION 15. REGULATORY INFORMATION

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

HSNO Approval Number

HSR001760

HSNO Controls

Approved handler certificate required

HSNO tracking 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:

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);

SAFETY DATA SHEET

Profender



Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	05.03.2019	122000001666	Date of first issue: 05.03.2019

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

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