

SAFETY DATA SHEETS

This SDS packet was issued with item:

078912725

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078912720 078912721 078912722 078912723 078912724 078912726

SAFETY DATA SHEET
Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**Product information**

Product Name: Profender Topical Solution
Synonyms: TGKKT-2106-0-1
SDS Number: 122000001666

Use : veterinary medicine

Company

BAYER HEALTHCARE LLC
Animal Health Division
12707 Shawnee Mission Parkway
(West 63rd)
Shawnee, KS 66216-1846
USA
(800) 633-3796

In case of emergency: (800) 422-9874
Chemtec: (800) 424-9300
BAYER INFORMATION PHONE: (800) 633-3796
INTERNATIONAL: (703) 527-3887

2. HAZARDS IDENTIFICATION**Emergency Overview**

WARNING! Combustible Liquid **Colour:** colourless **Form:** liquid **Odour:** weak.
May cause skin irritation. May cause eye irritation.

GHS Classification:

Eye irritation : Category 2
Specific target organ toxicity - repeated exposure : Category 2

GHS Label element:

Hazard pictograms :



Signal word : Warning

SAFETY DATA SHEET

Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

- Hazard statements** : H319 Causes serious eye irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
- Precautionary statements** : **Prevention:**
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.
Response:
P314 Get medical advice/ attention if you feel unwell.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P391 Collect spillage.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Weight percent	Components	CAS-No.
60 - 100%	Tradesecret	
7.94%	Praziquantel	55268-74-1
1 - 5%	Tradesecret	
1.984%	Emodepside (Bay 44-4400)	155030-63-0

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.

Contact Number: Use the Bayer Emergency Number in Section 1

SAFETY DATA SHEET

Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

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 firefighting: Fire may cause evolution of: Carbon monoxide (CO)
Carbon dioxide (CO₂)

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Use adequate ventilation.

Methods for 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.

Additional advice: No special precautions required.

Further Accidental Release Notes No special precautions required.

7. HANDLING AND STORAGE

Handling:

Avoid formation of aerosol. Only handle product with local exhaust ventilation. Avoid contact with skin, eyes and clothing.

No special protective measures against fire required.

Storage:

Storage temperature: < 77 °F (< 25 °C)
Do not freeze.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Lactic acid (50-21-5)

Emodepside (Bay 44-4400) (155030-63-0)

SAFETY DATA SHEET

Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

Respiratory protection:

Recommended Filter type: Organic vapor with prefilter

None required for consumer use of this product.

Hand protection:

Chemically resistant gloves.

None required for consumer use of this product.

Eye protection:

Safety glasses

None required for consumer use of this product.

Other protective measures:

Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	liquid	
Colour:	colourless	
Odour:	weak	
Odour Threshold:	No applicable information is available	
Melting point:	No applicable information is available	
Boiling point/boiling range:	ca. 190 °C	
Density:	1.081 g/cm ³ at 68 °F (20 °C)	DIN 51757
Bulk density:	No applicable information is available	
Vapour pressure:	No applicable information is available	
Viscosity, dynamic:	No applicable information is available	
Viscosity, kinematic:	No applicable information is available	
Flow time:	No applicable information is available	
Surface tension:	No applicable information is available	
Miscibility with water:	in all proportions at 68 °F (20 °C)	
Water solubility:	No applicable information is available	
pH:	No applicable information is available	
Relative density:	No applicable information is available	
Partition coefficient:	No applicable information is available	
Solubility(ies):	No applicable information is available	
Flash point:	176 °F (80 °C)	
Flammability (solid, gas):	No applicable information is available	
Ignition temperature:	No applicable information is available	
Explosion limits:	No applicable information is available	

SAFETY DATA SHEET

Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

10. STABILITY AND REACTIVITY

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

Materials to avoid: Oxidizing agents

Hazardous reactions: No data available

Thermal decomposition:

No data available

Hazardous decomposition products:
Carbon monoxide (CO), Carbon dioxide (CO₂)

Oxidizing properties:

No statements available.

Impact sensitivity:
No data available

11. TOXICOLOGICAL INFORMATION

Other information on toxicity:

Praziquantel

Ingestion of large quantities: Dizziness, Dizziness, Difficulty in breathing, Convulsions, Tiredness

Acute oral toxicity:

Acute toxicity estimate (ATE) > 2,000 mg/kg

May be harmful if swallowed.

Method: Calculation method

Calculated for GHS Classification and Labelling.

Acute dermal toxicity:

Acute toxicity estimate (ATE) > 2,000 mg/kg

May be harmful in contact with skin.

Method: Calculation method

Calculated for GHS Classification and Labelling.

Skin irritation:

Emodepside (Bay 44-4400)

Rabbit

Result: No skin irritation

Method: OECD 404

Eye irritation:

Praziquantel

Result: Mild eye irritation

SAFETY DATA SHEET

Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

Emodepside (Bay 44-4400)
Rabbit
Result: No eye irritation
Method: OECD 405

Sensitisation:

Emodepside (Bay 44-4400)

guinea pig

Result: Does not cause skin sensitisation.

Method: OECD 406

Subacute, subchronic and prolonged toxicity:

Emodepside (Bay 44-4400)

, Lowest observed effect level 4.2 mg/kg 50 ppm, Rat male Oral, Exposure time 4 weeks

Method: OECD 407

, Lowest observed effect level 5 mg/kg 50 ppm, Rat female Oral, Exposure time 4 weeks

Method: OECD 407

NOEL 5 mg/kg, Lowest observed effect level 10 mg/kg , Dog Oral, Exposure time 4 weeks

Method: OECD 407

NOEL 0.735 mg/kg 10 ppm, Lowest observed effect level 4.04 mg/kg 50 ppm, Rat male Oral,
Exposure time 13 Weeks

Method: OECD 408

NOEL 1.11 mg/kg 10 ppm, Lowest observed effect level 6.04 mg/kg 50 ppm, Rat female Oral,
Exposure time 13 Weeks

Method: OECD 408

NOEL 10.5 mg/kg 50 ppm, Lowest observed effect level 51.5 mg/kg 250 ppm, Mouse male Oral,
Exposure time 13 Weeks

Method: OECD 408

NOEL 16.8 mg/kg 50 ppm, Lowest observed effect level 79.1 mg/kg 250 ppm, Mouse female
Oral, Exposure time 13 Weeks

Method: OECD 408

Genotoxicity in vitro:

Praziquantel

Ames test

Result: negative, No evidence of a gene mutagenic effect.

Emodepside (Bay 44-4400)

Ames test Salmonella typhimurium

Result: negative

Method: OECD 471

V79-HPRT Forward Mutation Assay (Hamster V79-cells)

Result: negative

Method: OECD 476

SAFETY DATA SHEET

Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

Chromosome aberration test in vitro (Hamster V79-cells)

Result: **negative**

Method: **OECD 473**

Genotoxicity in vivo:

Emodepside (Bay 44-4400)

Micronucleus test, Mouse, Intraperitoneal

Result: **negative**

Method: **OECD 474**

Carcinogenicity:

Praziquantel

Result: Animal testing did not show any carcinogenic effects.

Emodepside (Bay 44-4400)

Experimental Data are currently not available.

Reproductive toxicity:

Praziquantel

Result: Animal testing did not show any effects on fertility.

Emodepside (Bay 44-4400)

Result: **Impairment of fertility in animal studies at doses which are harmful to the parent animals.**

Teratogenicity:

Praziquantel

Result: Did not show teratogenic effects in animal experiments.

Emodepside (Bay 44-4400)

Result: **Showed a toxic effect on the fetus in animal studies at doses which are harmful to the parent animals.**

Pharmaceutic effects:

Praziquantel

Anthelmintics

Emodepside (Bay 44-4400)

Antiparasitic agent

Carcinogenicity:

STOT - single exposure:

No data available

STOT - repeated exposure:

Components:

155030-63-0 :

Exposure routes: **Ingestion**

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

Assessment: **Causes damage to organs through prolonged or repeated exposure.**

12. ECOLOGICAL INFORMATION

SAFETY DATA SHEET

Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

General advice:

Do not allow to enter surface waters or groundwater.

Toxicity to fish:

Praziquantel

Acute Fish toxicity: LC50 17 mg/l

Duration of test: 24 h

Emodepside (Bay 44-4400)

LC0 > 0.01 mg/l

No mortality in the water-soluble range.

Toxicity to daphnia and other aquatic invertebrates:

Praziquantel

EC0 35 mg/l

EC100 100 mg/l

Emodepside (Bay 44-4400)

EC50 0.0021 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 48 h

Toxicity to algae:

Praziquantel

Cell multiplication inhibition test EbC50 140 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Cell multiplication inhibition test ErC50 77 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Cell multiplication inhibition test NOEbC 25 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Cell multiplication inhibition test NOErC 25 mg/l

tested on: Desmodesmus subspicatus (green algae) Duration of test: 72 h

Emodepside (Bay 44-4400)

EC0 0.01 mg/l

No mortality in the water-soluble range.

Toxicity to bacteria:

Praziquantel

EC50 > 1,000 mg/l

Duration of test: 3 h

Emodepside (Bay 44-4400)

EC50 > 10,000 mg/l

tested on: adapted and activated sludge micro-organism

Toxicity on soil-dwelling organisms

Emodepside (Bay 44-4400) LC50 > 1,000 mg/kg

Duration of test: 14 d

SAFETY DATA SHEET

Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

Biodegradability:

Praziquantel

0 %, Not readily biodegradable.

Emodepside (Bay 44-4400)

Not rapidly biodegradable

13. DISPOSAL CONSIDERATIONS

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

14. TRANSPORT INFORMATION

Land transport (CFR)

non-regulated

US Sea transport (IMDG)

non-regulated

US Air transport (ICAO / IATA cargo aircraft only)

non-regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)

non-regulated

International IATA

UN Number

3082

Description of the goods

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(EMODEPSIDE)

Class

9

Packaging group

III

Dangerous goods labels

9

Environmentally hazardous

yes

International IMDG

UN Number

3082

Description of the goods

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(EMODEPSIDE)

Class

9

Packaging group

III

IMDG-Labels

9

EmS Number

F-A

SAFETY DATA SHEET

Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

Marine pollutant

yes

15. REGULATORY INFORMATION

Other regulations: No statements available.**US. Toxic Substances Control Act**This product is excluded from TSCA regulation by
Section 3 (2)(B)(vi) when used for FDA application.**US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)****Components**

None

SARA Section 311/312 Hazard Categories

Exempt from SARA Section 311/312

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required**Components**

None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components

None

California Prop. 65**Weight percent**

0.1 - 1%

Components

2-tert-Butyl-4-methoxyphenol

CAS-No.

121-00-6

OSHA Hazcom Standard Rating

Hazardous

16. OTHER INFORMATION

NFPA 704M Rating

Health	1
Flammability	2
Reactivity	0
Other	0

0=Insignificant 1=Slight 2=Moderate 3=High 4=Extreme

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

SAFETY DATA SHEET

Profender Topical Solution

122000001666

Version 2.0

Revision Date 05/26/2015

Further information

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.