



SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

122000001666

BAY 60-7500 / Profender® Spot On Cat - Bulk

Version 5.3

Revision Date 29.01.2018

Print Date 12.05.2020

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

1.1 Product identifier

BAY 60-7500 / Profender® Spot On Cat - Bulk

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

Use of the : veterinary medicine, unfinished
Substance/Mixture

1.3 Details of the supplier of the safety data sheet

Company

Bayer AG

CHS - SCR

D-51368 LEVERKUSEN

Tel.: +49 (0) 214 30 52482

Mail: bhc-md-oeko@bayer.com

1.4 Emergency telephone number

In case of emergency: +49 (0) 214 30 99300 (Central Emergency Response Center Bayer)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS-Classification (according to EC 1272/2008):

Serious eye irritation, Category 2 (H319)

Specific target organ toxicity - repeated exposure, Category 2 (H373)

Hazardous to the aquatic environment - acute hazard, Category 1 (H400)

Hazardous to the aquatic environment - chronic hazard, Category 1 (H410)

2.2 Label elements

GHS-Labeling (according to EC 1272/2008):



Warning

Hazard statements:



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H319 Causes serious eye irritation.

H373 May cause damage to the blood system through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

P273 Avoid release to the environment.

P280 Wear 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.

Hazardous components which must be listed on the label:

155030-63-0 Emodepside

2.3 Other hazards

Other hazards which do not result in classification:

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a mixture within the meaning of Regulation (EC) No. 1907/2006.

Hazardous components

Praziquantel

Concentration [Weight percent] $\geq 2,5$ - < 10

CAS-No.: 55268-74-1

CAS name: 4H-Pyrazino(2,1-a)isoquinolin-4-one, 2-(cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-

EINECS-No.: 259-559-6

Synonyms: Biltricide, Embay 8440, Droncit, Pyquition

GHS Classification:



Acute Tox. 4 H312

Aquatic Chronic 3 H412

Lactic acid

Concentration [Weight percent] ≥ 1 - < 3

CAS-No.: 50-21-5

CAS name: Propanoic Acid, 2-Hydroxy-

EINECS-No.: 200-018-0

Synonyms: lactic acid



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GHS Classification:



Skin Irrit. 2 H315
Eye Dam. 1 H318

Emodepside

Concentration [Weight percent] $\geq 1 - < 2,5$

CAS-No.: 155030-63-0

CAS name: Cyclo[(.alpha.R)-.alpha.-hydroxy-4-(4-morpholinyl)benzenepropanoyl- N-methyl-L-leucyl-(2R)-2-hydroxypropanoyl-N-methyl-L-leucyl-(.alpha.R)- .alpha.-hydroxy-4-(4-morpholinyl)benzenepropanoyl-N-methyl-L-leucyl- (2R)-2-hydroxypropanoyl-N-methyl-L-leucyl]

Synonyms: PF 1022-221, Bay 44-4400

GHS Classification:



Acute Tox. 4 H302
STOT RE 1 H372
Aquatic Acute 1 H400
Aquatic Chronic 1 H410

M-Factor: 100

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of 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.

4.2 Most important acute symptoms/effects

Symptoms: No information available.

Risks: No information available.

4.3 Indication of any immediate medical attention and special treatment needed

No information available.



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5. FIREFIGHTING MEASURES

5.1 Extinguishing media

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

Unsuitable extinguishing media: High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Fire may cause evolution of: Nitrogen oxides (NO_x) Carbon monoxide (CO) Carbon dioxide (CO₂)

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

5.3 Advice for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Use with adequate ventilation.

6.2 Environmental precautions

Do not flush into surface water or sanitary sewer system.

6.3 Methods and materials for containment and cleaning up

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.

6.4 Reference to other sections

Additional advice: No special precautions required.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Handling:

Industrial uses: Avoid formation of aerosol. Use with local exhaust ventilation. Avoid contact with skin, eyes and clothing.



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No special protective measures against fire required.

7.2 Conditions for safe storage, including any incompatibilities

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.

Storage class in accordance to TRGS 510: 10 Combustible liquids not in Storage Class 3

7.3 Specific end use(s)

No statements available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Emodepside	155030-63-0	Bayer OES	0,03 mg/m ³	

8.2 Exposure controls

Personal protective measures:

Respiratory protection:

Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)

Hand protection:

Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.

Eye protection:

Safety glasses

Hygiene measures:

Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!

Other 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



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can be expected.
Wear suitable protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form:	liquid
Colour:	colourless
Odour:	weak
Melting point/range:	No statements available.
Boiling point/boiling range:	ca. 190 °C
Density:	1,081 g/cm ³ at 20 °C
Bulk density:	Not applicable
Vapour pressure:	No statements available.
Viscosity, dynamic:	No statements available.
Viscosity, kinematic:	No statements available.
Flow time:	No statements available.
Surface tension:	No statements available.
Water solubility:	No statements available.
Solubility(ies):	No statements available.
pH:	No statements available.
Corrosive to metal:	No statements available.
Partition coefficient (n-octanol/water):	Praziquantel log Pow: 2,012 Lactic acid log Pow: -0,62 Emodepside log Pow: 4,9 at pH 7
Flash point:	80 °C
Inflammability (solid, gaseous):	Not applicable
Explosion limits:	No statements available.

DIN 51757

9.2 Other information

Miscibility with water: in all proportions at 20 °C

10. STABILITY AND REACTIVITY



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10.1 Reactivity

No statements available.

Reactions with water / air:

No statements available.

Ignition temperature:

Emodepside

> 230 °C Swirled dust.BAM method

Burning number:

No statements available.

10.2 Chemical stability

No statements available.

Thermal decomposition:

No data available

Dust explosion characteristic number:

Not applicable

Dust explosion class:

Not applicable

Impact sensitivity:

No data available

Hazardous reactions:

No data available

Explosive properties:

No statements available.

10.3 Possibility of hazardous reactions

deflagration ability:

No statements available.

Smoldering combustion:

No statements available.

10.4 Conditions to avoid

Do not allow product to come in contact with:

Heat

Minimum ignition energy:

No data available

Oxidizing properties:

No statements available.



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10.5 Incompatible materials

Materials to avoid:

Oxidizing agents

10.6 Hazardous decomposition products

Nitrogen oxides (NO_x), Carbon monoxide (CO), Carbon dioxide (CO₂)

11. TOXICOLOGICAL INFORMATION

Toxicology Assessment:

Praziquantel

Acute effects: May be harmful if swallowed. Harmful in contact with skin.

Lactic acid

Acute effects: Causes skin irritation. Causes serious eye damage. May cause respiratory irritation.

Emodepside

Acute effects: Harmful if swallowed. May be harmful in contact with skin.

11.1 Information on toxicological effects

Other information on toxicity:

Praziquantel

Ingestion of large quantities:

Drowsiness

Difficulty in breathing

Ataxia (uncontrolled movements)

Tiredness

Acute oral toxicity:

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Acute toxicity estimate (ATE) > 2.000 mg/kg

Method: Calculation method

Acute toxicity estimate (ATE) > 2.000 mg/kg

Method: Calculation method

Praziquantel

LD₅₀ Rat: 2.840 mg/kg

The component/mixture is minimally toxic after single ingestion.

Lactic acid

LD₅₀ Rat: 3.543 mg/kg

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LD₅₀ Rat: > 500 - < 1.000 mg/kg

The component/mixture is moderately toxic after single ingestion.

Method: OECD 423



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Acute inhalation toxicity:

No statements available.

Acute dermal toxicity:

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Acute toxicity estimate (ATE) > 2.000 mg/kg

May be harmful in contact with skin.

Method: Calculation method

Calculated for GHS Classification and Labelling.

Acute toxicity estimate (ATE) > 2.000 mg/kg

Method: Calculation method

Praziquantel

The component/mixture is moderately toxic after single contact with skin.

Lactic acid

LD50 Rabbit: > 2.000 mg/kg

Emodepside

LD50 Rat: > 2.000 mg/kg

The component/mixture is minimally toxic after single contact with skin.

Method: OECD 402

Acute toxicity (other routes of administration):

No statements available.

Corrosivity:

No statements available.

Skin irritation:

Lactic acid

Result: Skin irritation

Emodepside

Rabbit

Result: No skin irritation

Method: OECD 404

Eye irritation:

Praziquantel

Result: May irritate eyes.

Lactic acid

Result: Risk of serious damage to eyes.

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Rabbit

Result: No eye irritation



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Method: OECD 405

Sensitisation:

Lactic acid

Result: Does not cause skin sensitisation.

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Guinea pig

Result: Does not cause skin sensitisation.

Method: OECD 406

Phototoxicity:

No statements available.

Subacute, subchronic and prolonged toxicity:

Emodepside

LOAEL 4,2 mg/kg 50 ppm

Rat male, Oral

Exposure time: 4 weeks

Method: OECD 407

NOAEL 16,8 mg/kg 50 ppm

LOAEL 79,1 mg/kg 250 ppm

Mouse female, Oral

Exposure time: 13 Weeks

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

Method: OECD 408

STOT - single exposure:

Praziquantel

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

STOT - repeated exposure:

Praziquantel

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

Emodepside

Route of exposure: Ingestion

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

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

Aspiration toxicity:

No statements available.

Genotoxicity in vitro:

Praziquantel

Ames test

Result: No indication of mutagenic effects.



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Lactic acid

Tests with bacteria and mammalian cells showed no evidence of genotoxic effects.

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Ames test Salmonella typhimurium

Result: negative

Method: OECD 471

V79-HPRT Forward Mutation Assay Hamster V79-cells

Result: negative

Method: OECD 476

Chromosome aberration test in vitro Hamster V79-cells

Result: negative

Method: OECD 473

Genotoxicity in vivo:

Emodepside

Micronucleus test, Mouse, intraperitoneal

Result: negative

Method: OECD 474

Carcinogenicity:

Praziquantel

Result: Animal testing did not show any carcinogenic effects.

Emodepside

Experimental Data are currently not available.

Fertility:

Praziquantel

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

Emodepside

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

Developmental toxicity:

Praziquantel

Result: Did not show teratogenic effects in animal experiments.

Emodepside

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

CMR classification:

Praziquantel

Carcinogenicity: Animal testing did not show any carcinogenic effects.

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



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Fertility: No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.

Human experience:

No statements available.

Neurotoxicity:

No statements available.

Neurological symptoms:

No statements available.

Pharmaceutic effects:

Praziquantel

Anthelmintics

Emodepside

Antiparasitic agent

12. ECOLOGICAL INFORMATION

Ecotoxicology Assessment

Praziquantel

Acute aquatic toxicity: Harmful to aquatic life.

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

Lactic acid

Acute aquatic toxicity: slightly water endangering

Emodepside

Acute aquatic toxicity: Very toxic to aquatic life.

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

12.1 Toxicity

Toxicity to fish:

Emodepside

LC0 > 0,01 mg/l

No mortality in the water-soluble range.

Toxicity to daphnia and other aquatic invertebrates:

Praziquantel

EC50 35 mg/l

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

Lactic acid

EC50 240 mg/l

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



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Emodepside

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

Test species: *Desmodesmus subspicatus* (green algae) Duration of test: 72 h

Cell multiplication inhibition test ErC₅₀ 77 mg/l

Test species: *Desmodesmus subspicatus* (green algae) Duration of test: 72 h

Cell multiplication inhibition test NOEbC 25 mg/l

Test species: *Desmodesmus subspicatus* (green algae) Duration of test: 72 h

Cell multiplication inhibition test NOErC 25 mg/l

Test species: *Desmodesmus subspicatus* (green algae) Duration of test: 72 h

Emodepside

EC₀ 0,01 mg/l

No mortality in the water-soluble range.

Toxicity to bacteria:

Praziquantel

EC₅₀ > 1.000 mg/l

Test species: activated sludge micro-organism

Duration of test: 3 h

Method: OECD 209

Emodepside

EC₅₀ > 10.000 mg/l

Test species: adapted and activated sludge micro-organism

Toxicity to fish (Chronic toxicity):

No statements available.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

No statements available.

Toxicity on soil-dwelling organisms:

Emodepside

LC₅₀ > 1.000 mg/kg

Duration of test: 14 d

Toxicity on other terrestrial non-mammal:

No statements available.

12.2 Persistence and degradability

Biodegradability:



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Praziquantel

0 %, Not rapidly biodegradable

Emodepside

Not rapidly biodegradable

Biochemical Oxygen Demand (BOD):

Lactic acid

0,45 mg/g, 5 d

0,60 mg/g, 20 d

Chemical Oxygen Demand (COD):

Praziquantel

2.340 mg/g, DIN 38414

Lactic acid

0,90 mg/g

BSB in proportion to CSB:

No statements available.

Dissolved organic carbon (DOC):

No statements available.

Adsorbed organic bound halogens (AOX):

Lactic acid

Product does not contain any organic halogens.

Theoretical biological oxygen requirement:

No statements available.

BSB in proportion to ThSB:

No statements available.

Total organic carbon (TOC):

No statements available.

Physico-chemical removability:

No statements available.

Stability in water:

No statements available.

Important degradation pathways:

No statements available.

Photodegradation:

No statements available.

M-Factor:

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100



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12.3 Bioaccumulative potential

Bioaccumulation:

No statements available.

Partition coefficient (n-octanol/water):

Praziquantel

log Pow: 2,012

Lactic acid

log Pow: -0,62

Emodepside

log Pow: 4,9

12.4 Mobility in soil

Environmental distribution:

No statements available.

Surface tension:

No statements available.

Stability in soil:

No statements available.

12.5 Results of PBT and vPvB assessment

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This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

General advice:

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Do not allow to enter surface waters or groundwater.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of as hazardous waste in compliance with local and national regulations. Drugs other than those mentioned in 18 01 07.

Contaminated packaging: Contaminated, empty containers are to be treated in the same way as the contents.



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14. TRANSPORT INFORMATION

The hazardous goods classification refers to the transportation of bulk goods. Under certain circumstances, regulation-specific relaxations and exemptions may be applied for the transportation of packaged goods intended for sale. This may lead to a labeling of the goods that differs from the classification listed here.

ADR/RID

- 14.1 UN Number : 3082
- 14.2 Description of the goods : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (EMODEPSIDE)
- 14.3 Hazard Identification Number : 90
- 14.4 Packaging group : III
- Dangerous goods labels : 9
- 14.5 Environmentally hazardous : yes

GGVS/GGVE

- 14.1 UN Number : 3082
- 14.2 Description of the goods : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (EMODEPSIDE)
- 14.3 Hazard Identification Number : 90
- Dangerous goods labels : 9
- 14.4 Packaging group : III
- 14.5 Environmentally hazardous : yes

ADNR

- 14.1 UN Number : 3082
- 14.2 Description of the goods : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (EMODEPSIDE)
- 14.3 Hazard Identification Number : 90
- 14.4 Packaging group : III
- Dangerous goods labels : 9
- 14.5 Environmentally hazardous : yes

IATA

- 14.1 UN Number : 3082
- 14.2 Description of the goods : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,



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N.O.S.
(EMODEPSIDE)
14.3 Class : 9
14.4 Packaging group : III
Dangerous goods labels : 9
14.5 Environmentally : yes
hazardous

IMDG

14.1 UN Number : 3082
14.2 Description of the goods : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(EMODEPSIDE)
14.3 Class : 9
14.4 Packaging group : III
IMDG-Labels : 9
EmS Number : F-A
14.5 Marine pollutant : yes

14.6 Special precautions for user

For personal protection see section 8.

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

not applicable

Limited quantity regulations applicable in accordance with chapter 3.4 RID/ADR in compliance with threshold value.

Other information : Combustible
Keep separated from foodstuffs

15. REGULATORY INFORMATION

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

National legislation

Water contaminating class (Germany):

WGK 2 (water endangering)

VwVwS (German Regulation) supplement 4

Major accidents regulations appendix I no.:

E1



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Guidelines and information sheets issued by the Chemical Industry Employers' Insurance Association:

M 053 /BGI 660 ("Protective measures when handling hazardous substances at work"), DGUV Information 213-083

15.2 Chemical safety assessment

No statements available.

16. OTHER INFORMATION

Full text of H-Statements mentioned in chapters 2 and 3

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H372	Causes damage to organs through prolonged or repeated exposure if swallowed.
H373	May cause damage to the blood system through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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

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.