

SAFETY DATA SHEETS

This SDS packet was issued with item:

078914591

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

078041529

SAFETY DATA SHEET

122000007040

Marquis (Ponazuril) EPM Paste

Version 2.0

Revision Date 07/31/2015

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

Product Name: Marquis (Ponazuril) EPM Paste
SDS Number: 122000007040

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
Chemtrec: (800) 424-9300
BAYER INFORMATION PHONE:(800) 633-3796
INTERNATIONAL:(703) 527-3887

2. HAZARDS IDENTIFICATION**Emergency Overview**

Colour: off-white **Form:** paste **Odour:** odourless.

GHS Classification:

Not a dangerous substance / mixture according to GHS.

GHS Label element:

Not a dangerous substance / mixture according to GHS.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Weight percent	Components	CAS-No.
15%	ponazuril	69004-04-2

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10 - 30%

Propane-1,2-diol

57-55-6

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

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: Hydrogen cyanide (hydrocyanic acid) Hydrogen fluoride Sulphur oxides Nitrogen oxides (NOx) Carbon oxides

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.

Methods for cleaning up: Cover spilled product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labeled, closable containers.

Additional advice: No special precautions required.

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**Further Accidental
Release Notes****No special precautions required.**

7. HANDLING AND STORAGE**Handling:**

Industrial uses: Avoid formation of aerosol. Avoid contact with skin, eyes and clothing.

No special protective measures against fire required.**Storage:**Storage temperature: 59 - 86 °F (15 - 30 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Propane-1,2-diol (57-55-6)**US. OARS. WEELs Workplace Environmental Exposure Level Guide
Time Weighted Average (TWA): 10 mg/m³ (Aerosol.)**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.

Hygiene measures:

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

Other protective measures:

Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	paste
Colour:	off-white
Odour:	odourless
Odour Threshold:	No applicable information is available

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Melting point:	No applicable information is available
Boiling point/boiling range:	No applicable information is available
Density:	1.06 - 1.1 g/cm ³
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:	No applicable information is available
Water solubility:	No applicable information is available
pH:	5.7 - 6
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	> 200 °F (> 93.33 °C)
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	No applicable information is available
Explosion limits:	No applicable information is available

10. STABILITY AND REACTIVITY

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

Heat

Exposure to sunlight.

Materials to avoid: Oxidizing agents

Hazardous reactions: None known.

Thermal decomposition:

No data available

Hazardous decomposition products:

Hydrogen cyanide (hydrocyanic acid), Hydrogen fluoride, Sulphur oxides, Nitrogen oxides (NO_x), Carbon oxides

Oxidizing properties:

No statements available.

Impact sensitivity:

No data available

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11. TOXICOLOGICAL INFORMATION**Acute oral toxicity:**

ponazuril

LD50 Rat: > 5,000 mg/kg

Propane-1,2-diol

LD50 Rat: 22,000 mg/kg

The substance or mixture has no acute oral toxicity

Acute inhalation toxicity:

Propane-1,2-diol

LC50 Rabbit: > 317 mg/l, 2 h

The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity:

Propane-1,2-diol

LD50 Rabbit: > 5,000 mg/kg

The substance or mixture has no acute dermal toxicity

Skin irritation:

Propane-1,2-diol

Rabbit

Result: No skin irritation

Eye irritation:

Propane-1,2-diol

Rabbit

Result: No eye irritation

Sensitisation:

Propane-1,2-diol

Human experience

Result: Does not cause skin sensitisation.

guinea pig

Result: Does not cause skin sensitisation.

Method: OECD 406

Subacute, subchronic and prolonged toxicity:

ponazuril

NOEL 150 ppm, Rat, Exposure time 105 d

Subchronic toxicity

NOEL 200 ppm, Dog, Exposure time 91 d

Subchronic toxicity

Propane-1,2-diol

NOEL 50,000 mg/kg, Rat Oral, Exposure time 24 month

NOEL 1 mg/l, Rat Inhalation, Exposure time 3 month

Number of exposures: Once daily

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Genotoxicity in vitro:

ponazuril

Ames test

Result: No evidence of a genotoxic effect.

Micronucleus test

Result: No indication of clastogenic effects.

Propane-1,2-diol

Ames test Bacteria

Dose: yes

Result: negative

Method: OECD 471

Mammalian cells

Result: negative

Method: OECD 476

Genotoxicity in vivo:

Propane-1,2-diol

Result: negative

Method: OECD 478

Carcinogenicity:

Propane-1,2-diol

Rat:

Exposure time: 2 a

Number of exposures: Once daily

Result: negative

Reproductive toxicity:

Propane-1,2-diol

Application Route: Oral

Rat, female: Test period: 18 d

NOAEL: 1600 mg/kg

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

Teratogenicity:

Propane-1,2-diol

Rat, male: Number of exposures: Once daily

Test period: 15 d

NOAEL: 1600 mg/l

Result: No indication of teratogenic effects.

Carcinogenicity:

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

STOT - single exposure:

No data available

STOT - repeated exposure:

No data available

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12. ECOLOGICAL INFORMATION**General advice:**

Do not allow to enter surface waters or groundwater. No data is available on the product itself.

Toxicity to fish:

ponazuril

LC50 10.3 mg/l

Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

LC50 88 mg/l

Test species: Lepomis macrochirus (Bluegill) Duration of test: 96 h

Propane-1,2-diol

Acute Fish toxicity: LC50 40,613 mg/l

Test species: Pimephales promelas (fathead minnow) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:

ponazuril

EC50 23.8 mg/l

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

Propane-1,2-diol

LC50 18,340 mg/l

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

Toxicity to algae:

Propane-1,2-diol

IC50 19,100 mg/l

tested on: Pseudokirchneriella subcapitata (green algae)

Toxicity to bacteria:

Propane-1,2-diol

NOEC 20,000 mg/l

tested on: Pseudomonas putida

Duration of test: 18 h

Biodegradability:

ponazuril

Not rapidly biodegradable

Propane-1,2-diol

87 - 92 %, 28 d rapidly biodegradable

Method: OECD 301 C

Bioaccumulation:

Propane-1,2-diol

Bioconcentration factor (BCF)

0.09

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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

<u>International IATA</u>	non-regulated
IMDG	non-regulated

15. REGULATORY INFORMATION

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

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

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists		
Weight percent	Components	CAS-No.
10 - 30%	Propane-1,2-diol	57-55-6

California Prop. 65

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To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard RatingNon-Hazardous

16. OTHER INFORMATION**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.

SAFETY DATA SHEET

122000007040

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

Product Name: Marquis (Ponazuril) EPM Paste
SDS Number: 122000007040

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
Chemtrec: (800) 424-9300
BAYER INFORMATION PHONE:(800) 633-3796
INTERNATIONAL:(703) 527-3887

2. HAZARDS IDENTIFICATION**Emergency Overview**

Colour: off-white **Form:** paste **Odour:** odourless.

GHS Classification:

Not a dangerous substance / mixture according to GHS.

GHS Label element:

Not a dangerous substance / mixture according to GHS.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Weight percent	Components	CAS-No.
15%	ponazuril	69004-04-2

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10 - 30%

Propane-1,2-diol

57-55-6

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

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: Hydrogen cyanide (hydrocyanic acid) Hydrogen fluoride Sulphur oxides Nitrogen oxides (NOx) Carbon oxides

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.

Methods for cleaning up: Cover spilled product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labeled, closable containers.

Additional advice: No special precautions required.

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**Further Accidental
Release Notes****No special precautions required.**

7. HANDLING AND STORAGE**Handling:**

Industrial uses: Avoid formation of aerosol. Avoid contact with skin, eyes and clothing.

No special protective measures against fire required.**Storage:**Storage temperature: 59 - 86 °F (15 - 30 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Propane-1,2-diol (57-55-6)**US. OARS. WEELs Workplace Environmental Exposure Level Guide
Time Weighted Average (TWA): 10 mg/m³ (Aerosol.)**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.

Hygiene measures:

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

Other protective measures:

Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	paste
Colour:	off-white
Odour:	odourless
Odour Threshold:	No applicable information is available

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Melting point:	No applicable information is available
Boiling point/boiling range:	No applicable information is available
Density:	1.06 - 1.1 g/cm ³
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:	No applicable information is available
Water solubility:	No applicable information is available
pH:	5.7 - 6
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	> 200 °F (> 93.33 °C)
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	No applicable information is available
Explosion limits:	No applicable information is available

10. STABILITY AND REACTIVITY**Conditions to avoid:** Do not allow product to come in contact with:

Heat

Exposure to sunlight.

Materials to avoid: Oxidizing agents**Hazardous reactions:** None known.**Thermal decomposition:**

No data available

Hazardous decomposition products:Hydrogen cyanide (hydrocyanic acid), Hydrogen fluoride, Sulphur oxides, Nitrogen oxides (NO_x), Carbon oxides**Oxidizing properties:**

No statements available.

Impact sensitivity:No data available

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11. TOXICOLOGICAL INFORMATION**Acute oral toxicity:**

ponazuril

LD50 Rat: > 5,000 mg/kg

Propane-1,2-diol

LD50 Rat: 22,000 mg/kg

The substance or mixture has no acute oral toxicity

Acute inhalation toxicity:

Propane-1,2-diol

LC50 Rabbit: > 317 mg/l, 2 h

The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity:

Propane-1,2-diol

LD50 Rabbit: > 5,000 mg/kg

The substance or mixture has no acute dermal toxicity

Skin irritation:

Propane-1,2-diol

Rabbit

Result: No skin irritation

Eye irritation:

Propane-1,2-diol

Rabbit

Result: No eye irritation

Sensitisation:

Propane-1,2-diol

Human experience

Result: Does not cause skin sensitisation.

guinea pig

Result: Does not cause skin sensitisation.

Method: OECD 406

Subacute, subchronic and prolonged toxicity:

ponazuril

NOEL 150 ppm, Rat, Exposure time 105 d

Subchronic toxicity

NOEL 200 ppm, Dog, Exposure time 91 d

Subchronic toxicity

Propane-1,2-diol

NOEL 50,000 mg/kg, Rat Oral, Exposure time 24 month

NOEL 1 mg/l, Rat Inhalation, Exposure time 3 month

Number of exposures: Once daily

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Genotoxicity in vitro:

ponazuril

Ames test

Result: No evidence of a genotoxic effect.

Micronucleus test

Result: No indication of clastogenic effects.

Propane-1,2-diol

Ames test Bacteria

Dose: yes

Result: negative

Method: OECD 471

Mammalian cells

Result: negative

Method: OECD 476

Genotoxicity in vivo:

Propane-1,2-diol

Result: negative

Method: OECD 478

Carcinogenicity:

Propane-1,2-diol

Rat:

Exposure time: 2 a

Number of exposures: Once daily

Result: negative

Reproductive toxicity:

Propane-1,2-diol

Application Route: Oral

Rat, female: Test period: 18 d

NOAEL: 1600 mg/kg

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

Teratogenicity:

Propane-1,2-diol

Rat, male: Number of exposures: Once daily

Test period: 15 d

NOAEL: 1600 mg/l

Result: No indication of teratogenic effects.

Carcinogenicity:

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

STOT - single exposure:

No data available

STOT - repeated exposure:No data available

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Version 2.0

Revision Date 07/31/2015

12. ECOLOGICAL INFORMATION**General advice:**

Do not allow to enter surface waters or groundwater. No data is available on the product itself.

Toxicity to fish:

ponazuril

LC50 10.3 mg/l

Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

LC50 88 mg/l

Test species: Lepomis macrochirus (Bluegill) Duration of test: 96 h

Propane-1,2-diol

Acute Fish toxicity: LC50 40,613 mg/l

Test species: Pimephales promelas (fathead minnow) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:

ponazuril

EC50 23.8 mg/l

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

Propane-1,2-diol

LC50 18,340 mg/l

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

Toxicity to algae:

Propane-1,2-diol

IC50 19,100 mg/l

tested on: Pseudokirchneriella subcapitata (green algae)

Toxicity to bacteria:

Propane-1,2-diol

NOEC 20,000 mg/l

tested on: Pseudomonas putida

Duration of test: 18 h

Biodegradability:

ponazuril

Not rapidly biodegradable

Propane-1,2-diol

87 - 92 %, 28 d rapidly biodegradable

Method: OECD 301 C

Bioaccumulation:

Propane-1,2-diol

Bioconcentration factor (BCF)

0.09

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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

IMDG

non-regulated

non-regulated

15. REGULATORY INFORMATION**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

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

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists**Weight percent****Components****CAS-No.**

10 - 30%

Propane-1,2-diol

57-55-6

California Prop. 65

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To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard RatingNon-Hazardous

16. OTHER INFORMATION**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.