

SAFETY DATA SHEETS

This SDS packet was issued with item:

078913001

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

078919764 078919765 078919766 078933107

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078040826 078040834 078912998

SAFETY DATA SHEET

122000000944

LEGEND Injectable Solution (10 mg/mL)

Version 2.0

Revision Date 08/11/2014

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**Product information****Product Name:** LEGEND Injectable Solution (10 mg/mL)**MSDS Number:** 122000000944**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****CAUTION! Colour:** clear, colourless **Form:** liquid

Product poses little or no hazard if spilled and no unusual hazard if involved in a fire.

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

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

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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: Carbon monoxide (CO)
Carbon dioxide (CO₂)

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

Further information: The product itself does not burn.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

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

Additional advice: No special precautions required.

Further Accidental Release Notes No special precautions required.

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7. HANDLING AND STORAGE**Handling:**No special precautions required.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Respiratory protection:**

Recommended Filter type: Organic vapor with prefilter

Hand protection:

Chemically resistant gloves.

Eye protection:

Safety glasses

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.

Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	No applicable information is available
Colour:	clear, colourless
Odour:	No applicable information is available
Odour Threshold:	No applicable information is available
Melting point:	No applicable information is available
Boiling point/boiling range:	ca. 100 °C
Density:	1.0 g/cm ³ at 68 °F (20 °C)
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
Water solubility:	No applicable information is available

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pH:	6.5 - 8.0 at (77 °F (25 °C)) (undiluted)
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	< 199.94 °F (93.3 °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:** no data available**Materials to avoid:** Oxidizing agents**Hazardous reactions:** None known.**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**Carcinogenicity:**

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

STOT - single exposure:

no data available

STOT - repeated exposure:no data available

12. ECOLOGICAL INFORMATION

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General advice:

Do not allow to enter surface waters or groundwater.

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**

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IMDG

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15. REGULATORY INFORMATION**Other regulations:** No statements available.**US. Toxic Substances Control Act**

This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical 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

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Revision Date 08/11/2014

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

None

California Prop. 65

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 Rating

Non-Hazardous

16. OTHER INFORMATION**NFPA 704M Rating**

Health	1
Flammability	1
Reactivity	0
Other	

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.

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.

1 Identification

- **Product identifier**
- **Trade name:** Marquis (Ponazuril) EPM Paste
- **Relevant identified uses of the substance or mixture and uses advised against Veterinary medicine**
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Merial Inc.
3239 Satellite Blvd.
Duluth, Ga. 30096-4640
1-888-MERIAL 1 (1-888-637-4251)
- **Emergency telephone number:**
Spill Information:
CHEMTREC® 1-800-424-9300
CHEMTREC® International 1+703-527-3887
International calls 011+703-527-3887
Reverse charges.
Emergency Information: CHEMTREC International 1 + 703-527-3887
Collect calls accepted

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**



- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Components:**

69004-04-2	Ponazuril	10-30%
57-55-6	Propylene Glycol	10-30%

Material Safety Data Sheet

ISO/DIS 11014 / 29 CFR 1910.1200 / ANSI Z400.1

Printing date 10/02/2015

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Trade name: Marquis (Ponazuril) EPM Paste

4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Remove to fresh air. Call a physician immediately.
- **After skin contact:**
After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.
- **After eye contact:**
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- **After swallowing:** If swallowed, seek medical advice immediately and show this container or label.
- **After self injection**
- **Most important symptoms and effects, both acute and delayed**
In case of symptomatic effect provide treatment to maintain life functions.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Water spray, carbon dioxide, foam or dry chemical powder.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
Fire may cause evolution of: Hydrogen cyanide (hydrocyanic acid), Hydrogen fluoride, Sulphur oxides, Nitrogen oxides (NOx), and Carbon oxides.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Prevent fire extinguishing water from contaminating surface water or the ground water system.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Keep away from ignition sources
- **Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **Methods and material 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.
- **Reference to other sections** No dangerous substances are released.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Avoid formation of aerosol. Only handle product with local exhaust ventilation. Avoid contact with skin, eyes and clothing. Take measures to prevent the build up of electrostatic charge. Keep away from open flames, hot surfaces and sources of ignition.

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Material Safety Data Sheet

ISO/DIS 11014 / 29 CFR 1910.1200 / ANSI Z400.1

Printing date 10/02/2015

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Trade name: Marquis (Ponazuril) EPM Paste

- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original container.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
- **Recommended storage temperature:** 59 - 86 °F (15 - 30 °C)
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Do not eat, drink, smoke or inhale.
Do not store food in the working area.
- **Breathing equipment:** Recommended Filter type: Organic vapor with prefilter
- **Protection of hands:** Chemically resistant gloves.
- **Eye protection:** Goggles
- **Body protection:** Not required under normal conditions of use.

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Paste
Color:	Off-white
Odor:	No odor
- **pH-value:** 5.7 - 6
- **Change in condition**
Melting point/Melting range: Undetermined.
- **Flash point:** > 200 °F (93.33 °C)
- **Ignition temperature:** Not Determined
- **Danger of explosion:** Product does not present an explosion hazard.
- **Specific gravity:** Not determined.
- **Solubility in / Miscibility with**

Water:	Not established
Organic solvents:	0.0 %

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· **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** Not Determined
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** Do not allow product to come in contact with: Heat, Exposure to sunlight.
- **Incompatible materials:** Oxidizing agents
- **Hazardous decomposition products:**
Hydrogen cyanide (hydrocyanic acid), Hydrogen fluoride, Sulphur oxides, Nitrogen oxides (NOx), and Carbon oxides.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** May cause irritation with symptoms of reddening and itching.
- **on the eye:** May cause irritation with symptoms of reddening, tearing and stinging.
- **Sensitization:** No sensitizing effects known.
- **Other information (about experimental toxicology):**
Inhalation of the glycol component is unlikely due to the low vapor Pressure. If misted or handled at elevated temperatures, high concentrations can produce irritation and/or difficulty breathing. May cause respiratory tract irritation with symptoms of coughing, sore throat and runny nose.
- **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
The substance is not subject to classification.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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Reviewed on 10/02/2015

Trade name: Marquis (Ponazuril) EPM Paste

- **Additional ecological information:**
- **General notes:**
 - Water hazard class 1 (Self-assessment): slightly hazardous for water
 - Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

15 Regulatory information

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

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

None of the ingredients are listed.

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Trade name: Marquis (Ponazuril) EPM Paste
· CA Proposition 65
· Chemicals known to cause cancer:

None of the ingredients are listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenesis potential categories
· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· MAK (German Maximum Workplace Concentration)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

· Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Merial or any of its subsidiaries or parents assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, Merial cannot guarantee that these are the only hazards that exist.

· Contact: MSDS Coordinator, msds@merial.com

· Date of preparation / last revision 10/02/2015 / -

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

- US -