

SAFETY DATA SHEETS

This SDS packet was issued with item:

078849451

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).

078848972 078848980 078848998 078849436 078849444 078917765



SAFETY DATA SHEET

Version Date: 10 May 2011

Supersedes: 02 October 2009

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Gamithromycin 15% Injection

Trade Name(s): ZACTRAN 150 MG/ML ANTIMICROBIAL
ZACTRAN 150 MG/ML SOLUTION FOR INJECTION FOR CATTLE

The following information is intended to give general health and safety guidance on the manufacturing, storage and transport of the mixture. Professional and non-professional users should consult label and package inserts for the proper use, storage and disposal of this mixture.

Chemical Family: Mixture: gamithromycin

Chemical Name: Mixture - NA

Synonyms: NA

Formula: Mixture - NA

Product Use: Gamithromycin 15% Injection is used in veterinary medicine for the treatment and prevention/control of bovine respiratory disease (BRD).

COMPANY ADDRESS Merial Limited
3239 Satellite Boulevard
Duluth, Georgia 30096-4640

EMERGENCY INFORMATION:

HEALTH INFORMATION 1-888-637-4251, option 3 (U.S.A. and Canada)

SPILL INFORMATION CHEMTREC® (In the U.S.A.): 1-800-424-9300
CHEMTREC® (International): 1-703-527-3887 (call collect)

2. HAZARDS IDENTIFICATION

Emergency Overview

Toxic to aquatic life. Do not eat, drink, or smoke when handling this mixture. Wash hands thoroughly after handling.

Environmental Hazard (GHS Classification)	Category	Pictogram	Signal Word	Hazard Statement
Acute Aquatic Hazard	2	-	-	Toxic to aquatic life (H401)

POTENTIAL HEALTH EFFECTS

The following potential human health effects are the results of the exposure to the mixture or extrapolated from the individual ingredients of the mixture.

EYE:	The mixture is not anticipated to be irritating to the eyes.
SKIN:	The mixture is not anticipated to produce skin irritation or sensitization.
INHALATION:	The mixture is not anticipated to produce vapors in a sufficient quantity that would be irritating to eyes, skin, nose and/or throat.
INGESTION:	The mixture is not anticipated to be harmful if swallowed.
CHRONIC EFFECTS:	The mixture is not anticipated to be carcinogenic, mutagenic, a reproductive toxin or a developmental toxin.
SIGNS AND SYMPTOMS OF EXPOSURE:	Signs and symptoms of exposure include allergic reactions. People with known hypersensitivity (allergy) to similar antibiotics (macrolide class) should avoid contact with Gamithromycin.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	None known.

POTENTIAL ENVIRONMENTAL EFFECTS	Some ingredients of this mixture are toxic to aquatic life. Avoid release to the environment.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No.	%W/V
Gamithromycin	145435-72-9	15
Non Hazardous Substances		85

4. FIRST AID MEASURES

EYE CONTACT:	In case of contact or if eyes become irritated during administration, immediately flush eyes with plenty of water for at least 15 minutes. If ocular irritation persists, seek medical attention.
SKIN CONTACT:	In case of contact or if skin become irritated during administration, immediately wash skin with soap and water. Remove contaminated clothing and shoes and launder before reuse. If skin irritation develops and persists or recurs, seek medical attention.
INHALATION:	If lungs become irritated or breathing is difficult during administration, move to fresh air and seek medical attention.
INGESTION:	If swallowed, seek immediate medical attention.

5. FIRE FIGHTING MEASURES

UNUSUAL FIRE AND EXPLOSION HAZARDS:	Prevent accumulation of vapors. When heated to decomposition, may produce oxides of carbon and nitrogen.
EXTINGUISHING MEDIA:	Carbon dioxide, dry chemical extinguishers, foam, water fog or spray. Large fires with "alcohol"-type foam extinguishers. Use extinguishing media appropriate for surrounding materials.
PROTECTION OF FIREFIGHTERS:	Fire fighters should wear approved/certified positive pressure self-contained breathing apparatus and full protective equipment.

6. ACCIDENTAL RELEASE MEASURES

For transportation-related and large spills call CHEMTREC at 1-800-424-9300. If outside the U.S.A., call CHEMTREC collect at 1-703-527-3887.

For small spills, use protective equipment as prescribed in Section 8. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material in sealed container as waste according to Section 13.

PERSONAL PRECAUTIONS: Evacuate unnecessary personnel and eliminate all sources of ignition. Follow protective measures provided under Personal Protection in Section 8.

ENVIRONMENTAL PRECAUTIONS: Avoid release to the environment.

METHODS FOR CLEANING UP: For small spills, soak up with absorbent materials and place in properly labeled containers.

7. HANDLING AND STORAGE

HANDLING: No smoking, eating, or drinking while using this mixture. Keep container tightly closed when not in use. Provide for adequate ventilation to prevent accumulation of vapors. Avoid prolonged or repeated exposure. Do not get in eyes, on skin or clothing. Keep away from incompatible materials (see Section 10).

PROTECTION AGAINST EXPLOSION AND FIRES: Keep ignition sources away. Do not smoke. Protect against electrostatic charges. Ground/bond container and receiving equipment. Use explosion-proof electrical, ventilating, and/or lighting equipment. Use only non-sparking tools.

STORAGE: Store in a well-ventilated place. Keep cool. Store locked up.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION (INDUSTRIAL)

The following ingredient(s) has exposure limits.

Component	OSHA PEL (TWA)		ACGIH TLV® (TWA)	
	ppm	mg/m ³	ppm	mg/m ³
Gamithromycin (CAS No. 145435-72-9)	-	-	-	-

ENGINEERING CONTROLS:	Use local exhaust ventilation to prevent accumulation of vapors.
EYE / FACE PROTECTION:	Wear chemical splash goggles when cleaning spilled mixture or if the potential for eye contact exists, wear safety glasses with side shields for normal handling.
SKIN PROTECTION:	Wear butyl rubber, neoprene, vinyl or other chemical resistant impervious gloves.
RESPIRATORY PROTECTION:	Wear approved/certified respirator when cleaning up spills. For normal use, ensure adequate exhaust ventilation.
GENERAL HYGIENE CONSIDERATIONS:	Do not eat, drink, or smoke while using this mixture. Wash hands thoroughly after use.
OTHER:	Provide emergency shower and eyewash facility in close proximity to use. Remove contaminated clothing and laundered before reuse or discard.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Color:	Clear
Odor:	No Odor
pH:	No data
Melting/Freezing Point:	No data
Boiling Point:	No data
Flash Point:	No data
Flammability:	No data
Lower Explosive Limit:	No data
Upper Explosive Limit:	No data
Autoignition Temperature:	No data
Decomposition Temperature:	No data
Vapor Pressure:	No data
Vapor Density:	No data
Solubility in Water:	No data
Specific gravity:	1.22 at 25°C
Viscosity:	No data
Partition Coefficient (n-octanol/Water):	Log K_{ow} -0.50 – 5.38 (ingredients) (computer generated)
Partition Coefficient (n-octanol/Air):	Log K_{oa} 6.855 – 31.675 (ingredients) (computer generated)
Soil Partition Coefficient:	Log K_{oc} 1.137 – 268.4 (ingredients) (computer generated)

10. STABILITY AND REACTIVITY

STABILITY: Stable under normal conditions.

CONDITIONS TO AVOID:	Avoid exposure to heat, sparks, or flame.
MATERIALS TO AVOID:	Avoid strong oxidizing agents
HAZARDOUS DECOMPOSITION PRODUCTS:	When heated to decomposition may produce oxides of carbon and nitrogen as well as other uncharacterized decomposition products.
HAZARDOUS POLYMERIZATION:	Will not occur.

11. TOXICOLOGICAL INFORMATION

POTENTIAL EXPOSURE ROUTES: This mixture may be encountered through skin contact, eye contact or ingestion.

The following toxicity data are derived from the ingredients of the mixture.

ACUTE ANIMAL TOXICITY DATA for MIXTURE:

		<u>Comments</u>
Oral LD₅₀ (mg/kg)	ATE = 5216	
Dermal LD₅₀ (mg/kg)	ATE = >2000	85% of the mixture consist of ingredients of unknown dermal toxicity
Inhalation LC₅₀ (mg/L)	NE	
Ocular Irritant	NE	
Dermal Irritant	Non-irritating	
Dermal Sensitizer	Non-sensitizer	

ATE – Acute Toxicity Estimate, NE = Not Established

The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the final mixture.

CARCINOGENICITY:	None of the ingredients in the mixture are considered to be carcinogenic.
MUTAGENICITY:	None of the ingredients in the mixture are considered to be mutagenic.
REPRODUCTIVE EFFECTS:	None of the ingredients in the mixture are considered to be a reproductive toxin.
TERATOGENICITY/ DEVELOPMENTAL EFFECTS:	None of the ingredients in the mixture are considered to be teratogenic or a developmental toxin.
SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:	None known
SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:	None known
INTERACTIONS WITH OTHER CHEMICALS WHICH ENHANCE TOXICITY:	None known

Other: People with known hypersensitivity (allergy) to similar antibiotics (macrolide class) should avoid contact with Gamithromycin.

12. ECOLOGICAL INFORMATION

The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the mixture.

TOXICITY: Based on computer modeling LC₅₀/EC₅₀ ranged from 0.26 to 799 mg/L for freshwater fish, invertebrates and plants. Based on computer modeling results, the mixture is considered a Category 2 Acute Aquatic Hazard (GHS standards).

PERSISTENCE AND DEGRADABILITY: Based upon computer modeling and physico-chemical characteristics of the ingredients in the mixture, the mixture is considered biodegradable in the environment.

BIOACCUMULATION POTENTIAL: Based on the K_{ow} of the ingredients in the mixture, some of the ingredients have the potential for bioaccumulation. However, fugacity modeling and biodegradation modeling suggest that the potential for bioaccumulation of those ingredients is low. Therefore, it is considered that the mixture will not persist in the environment.

MOBILITY IN SOIL: Based on the K_{oc} of the ingredients in the mixture and fugacity modeling, the mixture is not considered to have a high probability of mobility through the soil.

13. DISPOSAL CONSIDERATIONS

Responsibility for proper waste disposal is with the owner of the waste.

Dispose of all waste mixture and containers in accordance with national, regional, state and local regulations.

14. TRANSPORT INFORMATION

Air Transport ICAO-TI and IATA-DGR:

ICAO/IATA Class:	Not Regulated
UN/ID Number:	-
Label:	-
Packing Group:	-
Proper Shipping Name:	-

Maritime Transport IMDG:

IMDG Class:	Not Regulated
UN Number:	-
Label:	-
Packaging Group:	-
EMS Number:	-
Marine Pollutant:	-
Proper Shipping Name:	-

Land Transport ADR/RID: (cross-border)

ADR/RID Class:	Not Regulated
Danger Code (Kemler):	-
UN Number:	-
Packaging Group:	-

Proper Shipping Name: -

USDOT Regulations: Hazard Class: Not Regulated
 Identification Number: -
 Packing Group: -
 Proper Shipping Name: -
 (technical name)

15. REGULATORY INFORMATION

GHS Hazard Phrase: H401 Toxic to aquatic life

GHS Precautionary Phrases - Prevention: P280 Wear protective gloves/protective clothing/eye protection/face protection

GHS Precautionary Phrases - Response: P316 Call a POISON CENTER or doctor/physician if you feel unwell.
 P303 + P361 + P353 If on skin (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

GHS Precautionary Phrases - Disposal: P501 Dispose of contents/container to in accordance with local/regional/national/international regulation.

United States:

This mixture is exempt from classification under Environmental Protection Agency (EPA) Superfund Amendments and Reauthorization Act (SARA), Hazardous Substances List or Toxic Substances Control Act (TSCA).

STATE RIGHT-TO-KNOW STATUS:

Component	CA	NJ	PA	MA
Gamithromycin	Not listed	Not listed	Not Listed	Not listed

CA = California Proposition 65
 PA = Pennsylvania

NJ = New Jersey
 MA = Massachusetts

Canada:**CANADIAN WHMIS CLASS:**

The ingredients of this mixture have been classified in accordance with the hazard criteria of the CPR.

16. OTHER INFORMATION

Information contain within this document was based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (a.k.a. Purple Book).

KEY/LEGEND USED: NE = Not Established
 LD50 = The median lethal dose where 50% mortality is noted
 LC50 = The median lethal concentration (in air or solution) where 50%

mortality is noted

TWA = Time Weighted Average

OSHA PEL = Occupational Safety and Health Association Permissible
Exposure Limits

ACGIH TLV = American Conference of Governmental Industrial
Hygienists Threshold Limit Values

DISCLAIMER:

The requirements or recommendations of any relevant site or working procedure, system or policy in force or arising from any risk assessment involving the substance or mixture should take precedence over any of the guidance contained in this safety data sheet where there is a difference in the information given.

To the best of our knowledge, the information provided in this safety data sheet is accurate at the date of publication and will be updated as and when appropriate. However, neither Merial nor 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 may be described herein, Merial cannot guarantee that these are the only hazards that exist.



SAFETY DATA SHEET

Version Date: 10 May 2011

Supersedes: 02 October 2009

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Gamithromycin 15% Injection

Trade Name(s): ZACTRAN 150 MG/ML ANTIMICROBIAL
ZACTRAN 150 MG/ML SOLUTION FOR INJECTION FOR CATTLE

The following information is intended to give general health and safety guidance on the manufacturing, storage and transport of the mixture. Professional and non-professional users should consult label and package inserts for the proper use, storage and disposal of this mixture.

Chemical Family: Mixture: gamithromycin

Chemical Name: Mixture - NA

Synonyms: NA

Formula: Mixture - NA

Product Use: Gamithromycin 15% Injection is used in veterinary medicine for the treatment and prevention/control of bovine respiratory disease (BRD).

COMPANY ADDRESS Merial Limited
 3239 Satellite Boulevard
 Duluth, Georgia 30096-4640

EMERGENCY INFORMATION:

HEALTH INFORMATION 1-888-637-4251, option 3 (U.S.A. and Canada)

SPILL INFORMATION CHEMTREC® (In the U.S.A.): 1-800-424-9300
 CHEMTREC® (International): 1-703-527-3887 (call collect)

2. HAZARDS IDENTIFICATION

Emergency Overview

Toxic to aquatic life. Do not eat, drink, or smoke when handling this mixture. Wash hands thoroughly after handling.

Environmental Hazard (GHS Classification)	Category	Pictogram	Signal Word	Hazard Statement
Acute Aquatic Hazard	2	-	-	Toxic to aquatic life (H401)

POTENTIAL HEALTH EFFECTS

The following potential human health effects are the results of the exposure to the mixture or extrapolated from the individual ingredients of the mixture.

EYE:	The mixture is not anticipated to be irritating to the eyes.
SKIN:	The mixture is not anticipated to produce skin irritation or sensitization.
INHALATION:	The mixture is not anticipated to produce vapors in a sufficient quantity that would be irritating to eyes, skin, nose and/or throat.
INGESTION:	The mixture is not anticipated to be harmful if swallowed.
CHRONIC EFFECTS:	The mixture is not anticipated to be carcinogenic, mutagenic, a reproductive toxin or a developmental toxin.
SIGNS AND SYMPTOMS OF EXPOSURE:	Signs and symptoms of exposure include allergic reactions. People with known hypersensitivity (allergy) to similar antibiotics (macrolide class) should avoid contact with Gamithromycin.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	None known.

POTENTIAL ENVIRONMENTAL EFFECTS	Some ingredients of this mixture are toxic to aquatic life. Avoid release to the environment.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No.	%W/V
Gamithromycin	145435-72-9	15
Non Hazardous Substances		85

4. FIRST AID MEASURES

EYE CONTACT:	In case of contact or if eyes become irritated during administration, immediately flush eyes with plenty of water for at least 15 minutes. If ocular irritation persists, seek medical attention.
SKIN CONTACT:	In case of contact or if skin become irritated during administration, immediately wash skin with soap and water. Remove contaminated clothing and shoes and launder before reuse. If skin irritation develops and persists or recurs, seek medical attention.
INHALATION:	If lungs become irritated or breathing is difficult during administration, move to fresh air and seek medical attention.
INGESTION:	If swallowed, seek immediate medical attention.

5. FIRE FIGHTING MEASURES

UNUSUAL FIRE AND EXPLOSION HAZARDS:	Prevent accumulation of vapors. When heated to decomposition, may produce oxides of carbon and nitrogen.
EXTINGUISHING MEDIA:	Carbon dioxide, dry chemical extinguishers, foam, water fog or spray. Large fires with "alcohol"-type foam extinguishers. Use extinguishing media appropriate for surrounding materials.
PROTECTION OF FIREFIGHTERS:	Fire fighters should wear approved/certified positive pressure self-contained breathing apparatus and full protective equipment.

6. ACCIDENTAL RELEASE MEASURES

For transportation-related and large spills call CHEMTREC at 1-800-424-9300. If outside the U.S.A., call CHEMTREC collect at 1-703-527-3887.

For small spills, use protective equipment as prescribed in Section 8. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material in sealed container as waste according to Section 13.

PERSONAL PRECAUTIONS:	Evacuate unnecessary personnel and eliminate all sources of ignition. Follow protective measures provided under Personal Protection in Section 8.
ENVIRONMENTAL PRECAUTIONS:	Avoid release to the environment.
METHODS FOR CLEANING UP:	For small spills, soak up with absorbent materials and place in properly labeled containers.

7. HANDLING AND STORAGE

HANDLING:	No smoking, eating, or drinking while using this mixture. Keep container tightly closed when not in use. Provide for adequate ventilation to prevent accumulation of vapors. Avoid prolonged or repeated exposure. Do not get in eyes, on skin or clothing. Keep away from incompatible materials (see Section 10).
PROTECTION AGAINST EXPLOSION AND FIRES:	Keep ignition sources away. Do not smoke. Protect against electrostatic charges. Ground/bond container and receiving equipment. Use explosion-proof electrical, ventilating, and/or lighting equipment. Use only non-sparking tools.
STORAGE:	Store in a well-ventilated place. Keep cool. Store locked up.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION (INDUSTRIAL)

The following ingredient(s) has exposure limits.

Component	OSHA PEL (TWA)		ACGIH TLV® (TWA)	
	ppm	mg/m ³	ppm	mg/m ³
Gamithromycin (CAS No. 145435-72-9)	-	-	-	-

ENGINEERING CONTROLS:	Use local exhaust ventilation to prevent accumulation of vapors.
EYE / FACE PROTECTION:	Wear chemical splash goggles when cleaning spilled mixture or if the potential for eye contact exists, wear safety glasses with side shields for normal handling.
SKIN PROTECTION:	Wear butyl rubber, neoprene, vinyl or other chemical resistant impervious gloves.
RESPIRATORY PROTECTION:	Wear approved/certified respirator when cleaning up spills. For normal use, ensure adequate exhaust ventilation.
GENERAL HYGIENE CONSIDERATIONS:	Do not eat, drink, or smoke while using this mixture. Wash hands thoroughly after use.
OTHER:	Provide emergency shower and eyewash facility in close proximity to use. Remove contaminated clothing and laundered before reuse or discard.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Color:	Clear
Odor:	No Odor
pH:	No data
Melting/Freezing Point:	No data
Boiling Point:	No data
Flash Point:	No data
Flammability:	No data
Lower Explosive Limit:	No data
Upper Explosive Limit:	No data
Autoignition Temperature:	No data
Decomposition Temperature:	No data
Vapor Pressure:	No data
Vapor Density:	No data
Solubility in Water:	No data
Specific gravity:	1.22 at 25°C
Viscosity:	No data
Partition Coefficient (n-octanol/Water):	Log K_{ow} -0.50 – 5.38 (ingredients) (computer generated)
Partition Coefficient (n-octanol/Air):	Log K_{oa} 6.855 – 31.675 (ingredients) (computer generated)
Soil Partition Coefficient:	Log K_{oc} 1.137 – 268.4 (ingredients) (computer generated)

10. STABILITY AND REACTIVITY

STABILITY: Stable under normal conditions.

CONDITIONS TO AVOID:	Avoid exposure to heat, sparks, or flame.
MATERIALS TO AVOID:	Avoid strong oxidizing agents
HAZARDOUS DECOMPOSITION PRODUCTS:	When heated to decomposition may produce oxides of carbon and nitrogen as well as other uncharacterized decomposition products.
HAZARDOUS POLYMERIZATION:	Will not occur.

11. TOXICOLOGICAL INFORMATION

POTENTIAL EXPOSURE ROUTES: This mixture may be encountered through skin contact, eye contact or ingestion.

The following toxicity data are derived from the ingredients of the mixture.

ACUTE ANIMAL TOXICITY DATA for MIXTURE:

		<u>Comments</u>
Oral LD₅₀ (mg/kg)	ATE = 5216	
Dermal LD₅₀ (mg/kg)	ATE = >2000	85% of the mixture consist of ingredients of unknown dermal toxicity
Inhalation LC₅₀ (mg/L)	NE	
Ocular Irritant	NE	
Dermal Irritant	Non-irritating	
Dermal Sensitizer	Non-sensitizer	

ATE – Acute Toxicity Estimate, NE = Not Established

The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the final mixture.

CARCINOGENICITY:	None of the ingredients in the mixture are considered to be carcinogenic.
MUTAGENICITY:	None of the ingredients in the mixture are considered to be mutagenic.
REPRODUCTIVE EFFECTS:	None of the ingredients in the mixture are considered to be a reproductive toxin.
TERATOGENICITY/ DEVELOPMENTAL EFFECTS:	None of the ingredients in the mixture are considered to be teratogenic or a developmental toxin.
SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:	None known
SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:	None known
INTERACTIONS WITH OTHER CHEMICALS WHICH ENHANCE TOXICITY:	None known

Other: People with known hypersensitivity (allergy) to similar antibiotics (macrolide class) should avoid contact with Gamithromycin.

12. ECOLOGICAL INFORMATION

The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the mixture.

TOXICITY: Based on computer modeling LC₅₀/EC₅₀ ranged from 0.26 to 799 mg/L for freshwater fish, invertebrates and plants. Based on computer modeling results, the mixture is considered a Category 2 Acute Aquatic Hazard (GHS standards).

PERSISTENCE AND DEGRADABILITY: Based upon computer modeling and physico-chemical characteristics of the ingredients in the mixture, the mixture is considered biodegradable in the environment.

BIOACCUMULATION POTENTIAL: Based on the K_{ow} of the ingredients in the mixture, some of the ingredients have the potential for bioaccumulation. However, fugacity modeling and biodegradation modeling suggest that the potential for bioaccumulation of those ingredients is low. Therefore, it is considered that the mixture will not persist in the environment.

MOBILITY IN SOIL: Based on the K_{oc} of the ingredients in the mixture and fugacity modeling, the mixture is not considered to have a high probability of mobility through the soil.

13. DISPOSAL CONSIDERATIONS

Responsibility for proper waste disposal is with the owner of the waste.

Dispose of all waste mixture and containers in accordance with national, regional, state and local regulations.

14. TRANSPORT INFORMATION

Air Transport ICAO-TI and IATA-DGR:

ICAO/IATA Class:	Not Regulated
UN/ID Number:	-
Label:	-
Packing Group:	-
Proper Shipping Name:	-

Maritime Transport IMDG:

IMDG Class:	Not Regulated
UN Number:	-
Label:	-
Packaging Group:	-
EMS Number:	-
Marine Pollutant:	-
Proper Shipping Name:	-

Land Transport ADR/RID: (cross-border)

ADR/RID Class:	Not Regulated
Danger Code (Kemler):	-
UN Number:	-
Packaging Group:	-

Proper Shipping Name: -

USDOT Regulations: Hazard Class: Not Regulated
 Identification Number: -
 Packing Group: -
 Proper Shipping Name: -
 (technical name)

15. REGULATORY INFORMATION

GHS Hazard Phrase: H401 Toxic to aquatic life

GHS Precautionary Phrases - Prevention: P280 Wear protective gloves/protective clothing/eye protection/face protection

GHS Precautionary Phrases - Response: P316 Call a POISON CENTER or doctor/physician if you feel unwell.
 P303 + P361 + P353 If on skin (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

GHS Precautionary Phrases - Disposal: P501 Dispose of contents/container to in accordance with local/regional/national/international regulation.

United States:

This mixture is exempt from classification under Environmental Protection Agency (EPA) Superfund Amendments and Reauthorization Act (SARA), Hazardous Substances List or Toxic Substances Control Act (TSCA).

STATE RIGHT-TO-KNOW STATUS:

Component	CA	NJ	PA	MA
Gamithromycin	Not listed	Not listed	Not Listed	Not listed

CA = California Proposition 65
 PA = Pennsylvania

NJ = New Jersey
 MA = Massachusetts

Canada:**CANADIAN WHMIS CLASS:**

The ingredients of this mixture have been classified in accordance with the hazard criteria of the CPR.

16. OTHER INFORMATION

Information contain within this document was based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (a.k.a. Purple Book).

KEY/LEGEND USED: NE = Not Established
 LD50 = The median lethal dose where 50% mortality is noted
 LC50 = The median lethal concentration (in air or solution) where 50%

mortality is noted

TWA = Time Weighted Average

OSHA PEL = Occupational Safety and Health Association Permissible
Exposure Limits

ACGIH TLV = American Conference of Governmental Industrial
Hygienists Threshold Limit Values

DISCLAIMER:

The requirements or recommendations of any relevant site or working procedure, system or policy in force or arising from any risk assessment involving the substance or mixture should take precedence over any of the guidance contained in this safety data sheet where there is a difference in the information given.

To the best of our knowledge, the information provided in this safety data sheet is accurate at the date of publication and will be updated as and when appropriate. However, neither Merial nor 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 may be described herein, Merial cannot guarantee that these are the only hazards that exist.



SAFETY DATA SHEET

Version Date: 1 October 2016

Supersedes: 02 October 2009

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Gamithromycin 15% Injection

Trade Name(s): ZACTRAN 150 MG/ML ANTIMICROBIAL
ZACTRAN 150 MG/ML SOLUTION FOR INJECTION FOR CATTLE

The following information is intended to give general health and safety guidance on the manufacturing, storage and transport of the mixture. Professional and non-professional users should consult label and package inserts for the proper use, storage and disposal of this mixture.

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Chemical Name: Mixture - NA

Synonyms: NA

Formula: Mixture - NA

Product Use: Gamithromycin 15% Injection is used in veterinary medicine for the treatment and prevention/control of bovine respiratory disease (BRD).

COMPANY ADDRESS Merial Limited
3239 Satellite Boulevard
Duluth, Georgia 30096-4640

EMERGENCY INFORMATION:

HEALTH INFORMATION 1-888-637-4251, option 3 (U.S.A. and Canada)

SPILL INFORMATION CHEMTREC® (In the U.S.A.): 1-800-424-9300
CHEMTREC® (International): 1-703-527-3887 (call collect)

2. HAZARDS IDENTIFICATION

Emergency Overview

Toxic to aquatic life. Do not eat, drink, or smoke when handling this mixture. Wash hands thoroughly after handling.

Environmental Hazard (GHS Classification)	Category	Pictogram	Signal Word	Hazard Statement
Acute Aquatic Hazard	2	-	-	Toxic to aquatic life (H401)

POTENTIAL HEALTH EFFECTS

The following potential human health effects are the results of the exposure to the mixture or extrapolated from the individual ingredients of the mixture.

EYE:	The mixture is not anticipated to be irritating to the eyes.
SKIN:	The mixture is not anticipated to produce skin irritation or sensitization.
INHALATION:	The mixture is not anticipated to produce vapors in a sufficient quantity that would be irritating to eyes, skin, nose and/or throat.
INGESTION:	The mixture is not anticipated to be harmful if swallowed.
CHRONIC EFFECTS:	The mixture is not anticipated to be carcinogenic, mutagenic, a reproductive toxin or a developmental toxin.
SIGNS AND SYMPTOMS OF EXPOSURE:	Signs and symptoms of exposure include allergic reactions. People with known hypersensitivity (allergy) to similar antibiotics (macrolide class) should avoid contact with Gamithromycin.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	None known.

POTENTIAL ENVIRONMENTAL EFFECTS	Some ingredients of this mixture are toxic to aquatic life. Avoid release to the environment.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No.	%W/V
Gamithromycin	145435-72-9	15
Non Hazardous Substances		85

4. FIRST AID MEASURES

EYE CONTACT:	In case of contact or if eyes become irritated during administration, immediately flush eyes with plenty of water for at least 15 minutes. If ocular irritation persists, seek medical attention.
SKIN CONTACT:	In case of contact or if skin become irritated during administration, immediately wash skin with soap and water. Remove contaminated clothing and shoes and launder before reuse. If skin irritation develops and persists or recurs, seek medical attention.
INHALATION:	If lungs become irritated or breathing is difficult during administration, move to fresh air and seek medical attention.
INGESTION:	If swallowed, seek immediate medical attention.

5. FIRE FIGHTING MEASURES

UNUSUAL FIRE AND EXPLOSION HAZARDS:	Prevent accumulation of vapors. When heated to decomposition, may produce oxides of carbon and nitrogen.
EXTINGUISHING MEDIA:	Carbon dioxide, dry chemical extinguishers, foam, water fog or spray. Large fires with "alcohol"-type foam extinguishers. Use extinguishing media appropriate for surrounding materials.
PROTECTION OF FIREFIGHTERS:	Fire fighters should wear approved/certified positive pressure self-contained breathing apparatus and full protective equipment.

6. ACCIDENTAL RELEASE MEASURES

For transportation-related and large spills call CHEMTREC at 1-800-424-9300. If outside the U.S.A., call CHEMTREC collect at 1-703-527-3887.

For small spills, use protective equipment as prescribed in Section 8. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material in sealed container as waste according to Section 13.

PERSONAL PRECAUTIONS:	Evacuate unnecessary personnel and eliminate all sources of ignition. Follow protective measures provided under Personal Protection in Section 8.
ENVIRONMENTAL PRECAUTIONS:	Avoid release to the environment.
METHODS FOR CLEANING UP:	For small spills, soak up with absorbent materials and place in properly labeled containers.

7. HANDLING AND STORAGE

HANDLING:	No smoking, eating, or drinking while using this mixture. Keep container tightly closed when not in use. Provide for adequate ventilation to prevent accumulation of vapors. Avoid prolonged or repeated exposure. Do not get in eyes, on skin or clothing. Keep away from incompatible materials (see Section 10).
PROTECTION AGAINST EXPLOSION AND FIRES:	Keep ignition sources away. Do not smoke. Protect against electrostatic charges. Ground/bond container and receiving equipment. Use explosion-proof electrical, ventilating, and/or lighting equipment. Use only non-sparking tools.
STORAGE:	Store in a well-ventilated place. Keep cool. Store locked up.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION (INDUSTRIAL)

The following ingredient(s) has exposure limits.

Component	OSHA PEL (TWA)		ACGIH TLV® (TWA)	
	ppm	mg/m ³	ppm	mg/m ³
Gamithromycin (CAS No. 145435-72-9)	-	-	-	-

ENGINEERING CONTROLS:	Use local exhaust ventilation to prevent accumulation of vapors.
EYE / FACE PROTECTION:	Wear chemical splash goggles when cleaning spilled mixture or if the potential for eye contact exists, wear safety glasses with side shields for normal handling.
SKIN PROTECTION:	Wear butyl rubber, neoprene, vinyl or other chemical resistant impervious gloves.
RESPIRATORY PROTECTION:	Wear approved/certified respirator when cleaning up spills. For normal use, ensure adequate exhaust ventilation.
GENERAL HYGIENE CONSIDERATIONS:	Do not eat, drink, or smoke while using this mixture. Wash hands thoroughly after use.
OTHER:	Provide emergency shower and eyewash facility in close proximity to use. Remove contaminated clothing and laundered before reuse or discard.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Color:	Clear
Odor:	No Odor
pH:	No data
Melting/Freezing Point:	No data
Boiling Point:	No data
Flash Point:	No data
Flammability:	No data
Lower Explosive Limit:	No data
Upper Explosive Limit:	No data
Autoignition Temperature:	No data
Decomposition Temperature:	No data
Vapor Pressure:	No data
Vapor Density:	No data
Solubility in Water:	No data
Specific gravity:	1.22 at 25°C
Viscosity:	No data
Partition Coefficient (n-octanol/Water):	Log K_{ow} -0.50 – 5.38 (ingredients) (computer generated)
Partition Coefficient (n-octanol/Air):	Log K_{oa} 6.855 – 31.675 (ingredients) (computer generated)
Soil Partition Coefficient:	Log K_{oc} 1.137 – 268.4 (ingredients) (computer generated)

10. STABILITY AND REACTIVITY

STABILITY: Stable under normal conditions.

CONDITIONS TO AVOID:	Avoid exposure to heat, sparks, or flame.
MATERIALS TO AVOID:	Avoid strong oxidizing agents
HAZARDOUS DECOMPOSITION PRODUCTS:	When heated to decomposition may produce oxides of carbon and nitrogen as well as other uncharacterized decomposition products.
HAZARDOUS POLYMERIZATION:	Will not occur.

11. TOXICOLOGICAL INFORMATION

POTENTIAL EXPOSURE ROUTES: This mixture may be encountered through skin contact, eye contact or ingestion.

The following toxicity data are derived from the ingredients of the mixture.

ACUTE ANIMAL TOXICITY DATA for MIXTURE:

		<u>Comments</u>
Oral LD₅₀ (mg/kg)	ATE = 5216	
Dermal LD₅₀ (mg/kg)	ATE = >2000	85% of the mixture consist of ingredients of unknown dermal toxicity
Inhalation LC₅₀ (mg/L)	NE	
Ocular Irritant	NE	
Dermal Irritant	Non-irritating	
Dermal Sensitizer	Non-sensitizer	

ATE – Acute Toxicity Estimate, NE = Not Established

The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the final mixture.

CARCINOGENICITY:	None of the ingredients in the mixture are considered to be carcinogenic.
MUTAGENICITY:	None of the ingredients in the mixture are considered to be mutagenic.
REPRODUCTIVE EFFECTS:	None of the ingredients in the mixture are considered to be a reproductive toxin.
TERATOGENICITY/ DEVELOPMENTAL EFFECTS:	None of the ingredients in the mixture are considered to be teratogenic or a developmental toxin.
SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:	None known
SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:	None known
INTERACTIONS WITH OTHER CHEMICALS WHICH ENHANCE TOXICITY:	None known

Other: People with known hypersensitivity (allergy) to similar antibiotics (macrolide class) should avoid contact with Gamithromycin.

12. ECOLOGICAL INFORMATION

The following toxicity data are derived from the ingredients of the mixture, and are considered relevant to the mixture.

TOXICITY: Based on computer modeling LC₅₀/EC₅₀ ranged from 0.26 to 799 mg/L for freshwater fish, invertebrates and plants. Based on computer modeling results, the mixture is considered a Category 2 Acute Aquatic Hazard (GHS standards).

PERSISTENCE AND DEGRADABILITY: Based upon computer modeling and physico-chemical characteristics of the ingredients in the mixture, the mixture is considered biodegradable in the environment.

BIOACCUMULATION POTENTIAL: Based on the K_{ow} of the ingredients in the mixture, some of the ingredients have the potential for bioaccumulation. However, fugacity modeling and biodegradation modeling suggest that the potential for bioaccumulation of those ingredients is low. Therefore, it is considered that the mixture will not persist in the environment.

MOBILITY IN SOIL: Based on the K_{oc} of the ingredients in the mixture and fugacity modeling, the mixture is not considered to have a high probability of mobility through the soil.

13. DISPOSAL CONSIDERATIONS

Responsibility for proper waste disposal is with the owner of the waste.

Dispose of all waste mixture and containers in accordance with national, regional, state and local regulations.

14. TRANSPORT INFORMATION

Air Transport ICAO-TI and IATA-DGR:

ICAO/IATA Class:	Not Regulated
UN/ID Number:	-
Label:	-
Packing Group:	-
Proper Shipping Name:	-

Maritime Transport IMDG:

IMDG Class:	Not Regulated
UN Number:	-
Label:	-
Packaging Group:	-
EMS Number:	-
Marine Pollutant:	-
Proper Shipping Name:	-

Land Transport ADR/RID: (cross-border)

ADR/RID Class:	Not Regulated
Danger Code (Kemler):	-
UN Number:	-
Packaging Group:	-

Proper Shipping Name: -

USDOT Regulations: Hazard Class: Not Regulated
 Identification Number: -
 Packing Group: -
 Proper Shipping Name: -
 (technical name)

15. REGULATORY INFORMATION

GHS Hazard Phrase: H401 Toxic to aquatic life

GHS Precautionary Phrases - Prevention: P280 Wear protective gloves/protective clothing/eye protection/face protection

GHS Precautionary Phrases - Response: P316 Call a POISON CENTER or doctor/physician if you feel unwell.
 P303 + P361 + P353 If on skin (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

GHS Precautionary Phrases - Disposal: P501 Dispose of contents/container to in accordance with local/regional/national/international regulation.

United States:

This mixture is exempt from classification under Environmental Protection Agency (EPA) Superfund Amendments and Reauthorization Act (SARA), Hazardous Substances List or Toxic Substances Control Act (TSCA).

STATE RIGHT-TO-KNOW STATUS:

Component	CA	NJ	PA	MA
Gamithromycin	Not listed	Not listed	Not Listed	Not listed

CA = California Proposition 65
 PA = Pennsylvania

NJ = New Jersey
 MA = Massachusetts

Canada:**CANADIAN WHMIS CLASS:**

The ingredients of this mixture have been classified in accordance with the hazard criteria of the CPR.

16. OTHER INFORMATION

Information contain within this document was based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (a.k.a. Purple Book).

KEY/LEGEND USED: NE = Not Established
 LD50 = The median lethal dose where 50% mortality is noted
 LC50 = The median lethal concentration (in air or solution) where 50%

mortality is noted

TWA = Time Weighted Average

OSHA PEL = Occupational Safety and Health Association Permissible
Exposure Limits

ACGIH TLV = American Conference of Governmental Industrial
Hygienists Threshold Limit Values

DISCLAIMER:

The requirements or recommendations of any relevant site or working procedure, system or policy in force or arising from any risk assessment involving the substance or mixture should take precedence over any of the guidance contained in this safety data sheet where there is a difference in the information given.

To the best of our knowledge, the information provided in this safety data sheet is accurate at the date of publication and will be updated as and when appropriate. However, neither Merial nor 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 may be described herein, Merial cannot guarantee that these are the only hazards that exist.