

Zactran® Injectable solution

Version Revision Date: SDS Number: Date of last issue: 03/30/2022
2.0 12/28/2022 000000049048 Date of first issue: 03/30/2022

SECTION 1. IDENTIFICATION

Product name : Zactran® Injectable solution

Synonyms : with active ingredient: Gamythromycin
Zactran® Injectable solution 100 mL, 150 mg/mL, Zactran
swine, Zactran PP

Manufacturer or supplier's details

Company name of supplier : Boehringer Ingelheim AH USA

Address : Satellite Blvd Ste 500 3239
Duluth GA 30096
USA

Telephone : (678) 638-3000

Emergency telephone number : Int. Emergency Telephone number: +1 703-527-3887
US Emergency Telephone number: +1 703-741-5970

Prepared by : EHS-Services@Boehringer-Ingelheim.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product


Restrictions on use : Safety Data Sheet only for the professional user., For veteri-
nary use only, Refer to the product insert for complete instruc-
tions on usage

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Skin irritation : Category 2

Serious eye damage : Category 1

GHS label elements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H315 Causes skin irritation.
H318 Causes serious eye damage.

Zactran® Injectable solution

Version 2.0 Revision Date: 12/28/2022 SDS Number: 000000049048 Date of last issue: 03/30/2022
Date of first issue: 03/30/2022

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

Other hazards

This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)
The pharmacological effect of the medicament has to be considered (see package leaflet).

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
1,3-dioxolan-4-ylmethanol	5464-28-8	>= 30 - < 50
Gamithromycin	145435-72-9	>= 10 - < 20
succinic acid	110-15-6	>= 1 - < 5
Monothioglycerol	96-27-5	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
(show the package insert where possible).
First Aid responders should pay attention to self-protection and use the recommended protective clothing
Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.

If inhaled : Move to fresh air.

In case of skin contact : Wash off immediately with plenty of water.

In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.

Zactran® Injectable solution

Version	Revision Date:	SDS Number:	Date of last issue: 03/30/2022
2.0	12/28/2022	000000049048	Date of first issue: 03/30/2022

If swallowed	:	Rinse mouth. Drink plenty of water.
Most important symptoms and effects, both acute and delayed	:	Causes skin irritation. Causes serious eye damage.
Notes to physician	:	Observe the summary of product characteristics of proprietary medicinal products Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water Dry chemical Foam Carbon dioxide (CO ₂)
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	In case of fire and/or explosion do not breathe fumes.
Hazardous combustion products	:	Carbon oxides
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Wear personal protective equipment. Ensure adequate ventilation. High risk of slipping due to leakage/spillage of product.
Environmental precautions	:	Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Pick up and transfer to properly labelled containers. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	No special protective measures against fire required.
---	---	---

Zactran® Injectable solution

Version 2.0 Revision Date: 12/28/2022 SDS Number: 000000049048 Date of last issue: 03/30/2022
Date of first issue: 03/30/2022

- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
- Conditions for safe storage : Refer to the product insert for instructions on storage.
- Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Observe joint storage prohibition.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	Basis	Category	Values	Remarks
Gamithromycin 145435-72-9	BIEL	3A	60 µg/m ³	
	BIPC	1b		

Abbreviations:

BIEL = Boehringer Ingelheim Exposure Limit (internal value)

BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)

BIPC = Boehringer Ingelheim Pregnancy Category

BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.

- Engineering measures** : Local exhaust
Emergency sprinkling nozzle

Personal protective equipment

- Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.
- Hand protection
Material : Nitrile rubber
- Remarks : The break through time depends amongst other things on the material, the thickness and the type of glove and therefore has to be measured for each case.
- Eye protection : Tightly fitting safety goggles
Face-shield
(Not necessary when using full face mask)
- Skin and body protection : Laboratory: laboratory coat; Factory: disposable Overall.
Wear as appropriate:

Zactran® Injectable solution

Version	Revision Date:	SDS Number:	Date of last issue: 03/30/2022
2.0	12/28/2022	000000049048	Date of first issue: 03/30/2022

Complete suit protecting against chemicals

Protective measures : Handle in accordance with good industrial hygiene and safety practice.
Avoid contact with skin, eyes and clothing.
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : colourless, light yellow

Odour : No data available

pH : No data available

Melting point/range : Not applicable

Boiling point/boiling range : No data available

Flash point : No data available

Flammability (liquids) : No data available

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Bulk density : Not applicable

Zactran® Injectable solution

Version 2.0 Revision Date: 12/28/2022 SDS Number: 000000049048 Date of last issue: 03/30/2022
Date of first issue: 03/30/2022

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available

Explosive properties : Not tested

Oxidizing properties : No data available

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

1,3-dioxolan-4-ylmethanol:

Zactran® Injectable solution

Version Revision Date: SDS Number: Date of last issue: 03/30/2022
2.0 12/28/2022 000000049048 Date of first issue: 03/30/2022

Acute oral toxicity : Assessment: Toxic effects cannot be excluded

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Assessment: Toxic effects cannot be excluded

Gamithromycin:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rabbit, male and female): > 2,000 mg/kg

Acute toxicity (other routes of administration) : LD50: > 2,000 mg/kg
Application Route: subcutaneous

succinic acid:

Acute oral toxicity : LD50 (Rat): > 8,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 1,306 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : Remarks: No data available

Monothioglycerol:

Acute oral toxicity : LD50 (Rat, male and female): 648 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rabbit): 673 mg/kg
Method: OECD Test Guideline 402

Skin corrosion/irritation

Causes skin irritation.

Components:**1,3-dioxolan-4-ylmethanol:**

Remarks : No data available

Gamithromycin:

Species : Rabbit
Result : Skin irritation

succinic acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Zactran® Injectable solution

Version Revision Date: SDS Number: Date of last issue: 03/30/2022
2.0 12/28/2022 000000049048 Date of first issue: 03/30/2022

Monothioglycerol:

Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:**1,3-dioxolan-4-ylmethanol:**

Result : Irritation to eyes, reversing within 21 days

Gamithromycin:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

succinic acid:

Species : Rabbit
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

Monothioglycerol:

Species : Rabbit
Result : Mildly irritating.

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**1,3-dioxolan-4-ylmethanol:**

Remarks : No data available

Gamithromycin:

Method : DEREK
Result : Alert for skin sensitization

succinic acid:

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Method : OECD Test Guideline 429
Result : negative

Test Type : Maximisation Test
Species : Guinea pig
Method : OECD Test Guideline 406

Zactran® Injectable solution

Version 2.0 Revision Date: 12/28/2022 SDS Number: 000000049048 Date of last issue: 03/30/2022
Date of first issue: 03/30/2022

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Remarks: No data available

Monothioglycerol:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**1,3-dioxolan-4-ylmethanol:**

Remarks : No data available

Gamithromycin:

Species : Rat
Application Route : Ingestion
Exposure time : 2 years
Dose : 10, 30, 100 mg/kg/day
NOAEL : 10 mg/kg bw/day
Remarks : Did not show carcinogenic effects in animal experiments.

Species : Mouse, male
Application Route : Ingestion
Exposure time : 18 months
Dose : 30, 110,325 mg/kg/day
NOAEL : 30 mg/kg bw/day
Remarks : Did not show carcinogenic effects in animal experiments.

succinic acid:

Remarks : No data available

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Zactran® Injectable solution

Version 2.0 Revision Date: 12/28/2022 SDS Number: 000000049048 Date of last issue: 03/30/2022
Date of first issue: 03/30/2022

Components:**1,3-dioxolan-4-ylmethanol:**

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Gamithromycin:

Effects on fertility : Test Type: Two-generation study
Species: Rat
Application Route: Ingestion
Fertility: NOEL: 30 mg/kg body weight
Method: OECD Test Guideline 416

Effects on foetal development : Test Type: Two-generation study
Species: Rat
Application Route: Ingestion
Dose: 10,30,100 mg/kg/day
General Toxicity Maternal: NOEL: 30 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 10 mg/kg body weight

Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Dose: 150, 300, 450 mg/kg/day
General Toxicity Maternal: NOAEL: < 150 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 150 mg/kg body weight

succinic acid:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure

Not classified based on available information.

Components:**1,3-dioxolan-4-ylmethanol:**

Remarks : No data available

Gamithromycin:

Remarks : No data available

succinic acid:

Remarks : No data available

STOT - repeated exposure

Not classified based on available information.

Zacran® Injectable solution

Version 2.0 Revision Date: 12/28/2022 SDS Number: 000000049048 Date of last issue: 03/30/2022
Date of first issue: 03/30/2022

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : Remarks: No data available

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Gamithromycin:

Toxicity to fish : NOEC (Danio rerio (zebra fish)): \geq 100 mg/l
Exposure time: 96 h

LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : NOEC (Daphnia magna (Water flea)): \geq 81 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

EC50 (Daphnia magna (Water flea)): > 81 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC10 (Anabaena flos-aquae (cyanobacterium)): 0.0242 mg/l
End point: Growth rate
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0356 mg/l
End point: Growth rate
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 0.0814 mg/l
End point: Growth rate
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Zactran® Injectable solution

Version 2.0 Revision Date: 12/28/2022 SDS Number: 000000049048 Date of last issue: 03/30/2022
Date of first issue: 03/30/2022

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : MIC (Escherichia coli): 16 - 64 mg/l

succinic acid:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : EC50 (activated sludge): > 300 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Monothioglycerol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 35 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 11 mg/l
Exposure time: 48 h
Test Type: flow-through test
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 11 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): 3.4 mg/l
Exposure time: 72 h
Test Type: static test

Zactran® Injectable solution

Version Revision Date: SDS Number: Date of last issue: 03/30/2022
2.0 12/28/2022 000000049048 Date of first issue: 03/30/2022

Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Persistence and degradability**Components:****1,3-dioxolan-4-ylmethanol:**

Biodegradability : Result: No data available

Gamithromycin:

Biodegradability : Result: Not readily biodegradable.

succinic acid:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 95.55 %
Exposure time: 28 d
Method: OECD 301 E Guideline

Monothioglycerol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 80.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Bioaccumulative potential**Components:****1,3-dioxolan-4-ylmethanol:**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-
octanol/water : Remarks: No data available

Gamithromycin:

Bioaccumulation : Remarks: An appreciable bioaccumulation potential is to be expected (log P(o/w) > 3).

Partition coefficient: n-
octanol/water : log Pow: 3.28 - 4.92 (77 °F / 25 °C)

succinic acid:

Bioaccumulation : Bioconcentration factor (BCF): 3
Remarks: No bioaccumulation is to be expected (log P(o/w)<1).

Partition coefficient: n-
octanol/water : log Pow: -0.59

Zactran® Injectable solution

Version Revision Date: SDS Number: Date of last issue: 03/30/2022
2.0 12/28/2022 000000049048 Date of first issue: 03/30/2022

Monothioglycerol:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log P(o/w)<1).

Partition coefficient: n- : log Pow: < 0 (68 °F / 20 °C)
octanol/water : Method: OECD Test Guideline 117

Mobility in soil**Components:****1,3-dioxolan-4-ylmethanol:**

Distribution among environ- : Remarks: No data available
mental compartments

Gamithromycin:

Distribution among environ- : Remarks: No data available
mental compartments

succinic acid:

Distribution among environ- : Remarks: No data available
mental compartments

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:**1,3-dioxolan-4-ylmethanol:**

Additional ecological infor- : No data available
mation

Gamithromycin:

Additional ecological infor- : No data available
mation

succinic acid:

Additional ecological infor- : Causes damage effect's by pH- movement
mation

Zactran® Injectable solution

Version	Revision Date:	SDS Number:	Date of last issue: 03/30/2022
2.0	12/28/2022	000000049048	Date of first issue: 03/30/2022

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

UN/ID No. : UN 3082
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
 (Gamithromycin)
 Class : 9
 Packing group : III
 Labels : Miscellaneous Dangerous Goods
 Packing instruction (cargo aircraft) : 964
 Packing instruction (passenger aircraft) : 964
 Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
 N.O.S.
 (Gamithromycin)
 Class : 9
 Packing group : III
 Labels : 9
 EmS Code : F-A, S-F
 Marine pollutant : yes

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

Not applicable for product as supplied.

National Regulations

49 CFR

UN/ID/NA number : UN 3082
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
 (Gamithromycin)
 Class : 9
 Packing group : III
 Labels : CLASS 9
 ERG Code : 171
 Marine pollutant : yes

Zactran® Injectable solution

Version	Revision Date:	SDS Number:	Date of last issue: 03/30/2022
2.0	12/28/2022	000000049048	Date of first issue: 03/30/2022

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Skin corrosion or irritation
Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

succinic acid	110-15-6	>= 1 - < 5 %
---------------	----------	--------------

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

1,3-dioxolan-4-ylmethanol	5464-28-8
Gamithromycin	145435-72-9
succinic acid	110-15-6

Maine Chemicals of High Concern

Zactran® Injectable solution

Version 2.0 Revision Date: 12/28/2022 SDS Number: 000000049048 Date of last issue: 03/30/2022
Date of first issue: 03/30/2022

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The components of this product are reported in the following inventories:

TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. 1,3-dioxolan-4-ylmethanol Gamithromycin
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
TECI	:	Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

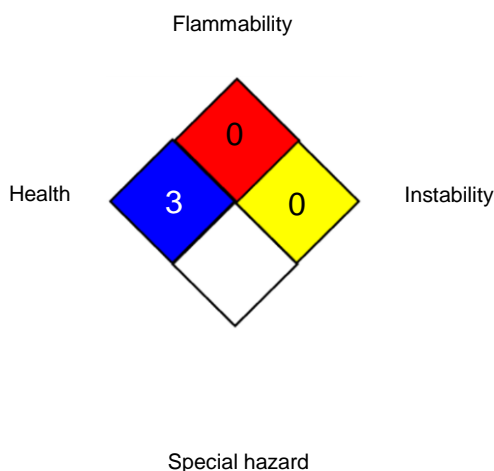
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION**Further information**

Zactran® Injectable solution

Version 2.0 Revision Date: 12/28/2022 SDS Number: 000000049048 Date of last issue: 03/30/2022
Date of first issue: 03/30/2022

NFPA 704:



HMIS® IV:

HEALTH	/	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Zactran® Injectable solution

Version	Revision Date:	SDS Number:	Date of last issue: 03/30/2022
2.0	12/28/2022	000000049048	Date of first issue: 03/30/2022

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

Revision Date : 12/28/2022

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

US / EN