

**Gentamicin / Betamethasone Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 04/09/2022  
6.7                07/22/2022                434583-00019            Date of first issue: 01/06/2016

---

**SECTION 1. IDENTIFICATION**

Product name                                : Gentamicin / Betamethasone Formulation  
Other means of identification            : No data available

**Manufacturer or supplier's details**

Company name of supplier                : Merck & Co., Inc  
Address                                        : 126 E. Lincoln Avenue  
    : Rahway, New Jersey U.S.A. 07065  
Telephone                                    : 908-740-4000  
Emergency telephone                      : 1-908-423-6000  
E-mail address                              : EHSDATASTEWARD@merck.com

**Recommended use of the chemical and restrictions on use**


Recommended use                         : Veterinary product  
  
Restrictions on use                        : Not applicable

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the Hazardous Products Regulations**

Reproductive toxicity                     : Category 1A  
  
Specific target organ toxicity            : Category 1 (Pituitary gland, Immune system, muscle, thymus  
- repeated exposure                      : gland, Blood, Adrenal gland)

**GHS label elements**

Hazard pictograms                        : 

Signal Word                                : Danger

Hazard Statements                        : H360D May damage the unborn child.  
    : H372 Causes damage to organs (Pituitary gland, Immune  
    : system, muscle, thymus gland, Blood, Adrenal gland) through  
    : prolonged or repeated exposure.

Precautionary Statements                : **Prevention:**  
    : P201 Obtain special instructions before use.  
    : P202 Do not handle until all safety precautions have been read  
    : and understood.  
    : P260 Do not breathe mist or vapors.  
    : P264 Wash skin thoroughly after handling.  
    : P270 Do not eat, drink or smoke when using this product.  
    : P280 Wear protective gloves, protective clothing, eye protection  
    : and face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical attention.

## Gentamicin / Betamethasone Formulation

Version 6.7      Revision Date: 07/22/2022      SDS Number: 434583-00019      Date of last issue: 04/09/2022  
 Date of first issue: 01/06/2016

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Polyethylene glycol stearate	Ethoxylated stearic acid	9004-99-3	5
Gentamicin	No data available	1403-66-3	0.49
Betamethasone	No data available	378-44-9	0.1

**SECTION 4. FIRST AID MEASURES**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES**

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
6.7	07/22/2022	434583-00019	Date of first issue: 01/06/2016

---

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
- 

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g., by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
- 

### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

## Gentamicin / Betamethasone Formulation

Version 6.7      Revision Date: 07/22/2022      SDS Number: 434583-00019      Date of last issue: 04/09/2022  
 Date of first issue: 01/06/2016

- Advice on safe handling** : Do not get on skin or clothing.  
 Do not breathe mist or vapors.  
 Do not swallow.  
 Avoid contact with eyes.  
 Wash skin thoroughly after handling.  
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
 Keep container tightly closed.  
 Do not eat, drink or smoke when using this product.  
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage** : Keep in properly labeled containers.  
 Store locked up.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.
- Materials to avoid** : Do not store with the following product types:  
 Strong oxidizing agents  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Polyethylene glycol stearate	9004-99-3	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Inhalable)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable)	3 mg/m <sup>3</sup>	CA BC OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Gentamicin	1403-66-3	TWA	0.1 mg/m <sup>3</sup> (OEB 2)	Internal
Further information: OTO				
Betamethasone	378-44-9	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

- Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
6.7	07/22/2022	434583-00019	Date of first issue: 01/06/2016

---

protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

### Personal protective equipment

- |                          |   |   |
|--------------------------|---|---|
| Respiratory protection   | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  |
| Filter type              | : | Particulates type   |
| Hand protection          | : |   |
| Material                 | : | Chemical-resistant gloves   |
| Remarks                  | : | Consider double gloving.  |
| Eye protection           | : | Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.  |
| Skin and body protection | : | Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.   |
| Hygiene measures         | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

---

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- |                              |   |                   |
|------------------------------|---|-------------------|
| Appearance                   | : | liquid            |
| Color                        | : | No data available |
| Odor                         | : | No data available |
| Odor Threshold               | : | No data available |
| pH                           | : | No data available |
| Melting point/freezing point | : | No data available |

**Gentamicin / Betamethasone Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 04/09/2022  
6.7                07/22/2022              434583-00019            Date of first issue: 01/06/2016

---

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
  Water solubility : No data available

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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
  Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : No data available

---

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

**Gentamicin / Betamethasone Formulation**

Version 6.7      Revision Date: 07/22/2022      SDS Number: 434583-00019      Date of last issue: 04/09/2022  
Date of first issue: 01/06/2016

---

Hazardous decomposition products : No hazardous decomposition products are known.

---

**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

**Components:****Polyethylene glycol stearate:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

**Gentamicin:**

Acute oral toxicity : LD50 (Rat): 8,000 - 10,000 mg/kg

LD50 (Mouse): 10,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg  
Application Route: Intravenous  
  
LD50 (Rat): 371 - 384 mg/kg  
Application Route: Intramuscular  
  
LDLo (Monkey): 30 mg/kg  
Application Route: Intravenous

**Betamethasone:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
  
LD50 (Mouse): > 4,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0.4 mg/l  
Exposure time: 4 h

**Gentamicin / Betamethasone Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 04/09/2022  
6.7                07/22/2022                434583-00019            Date of first issue: 01/06/2016

---

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Polyethylene glycol stearate:**

Species                                : Rabbit  
Method                                 : Draize Test  
Result                                  : No skin irritation

**Gentamicin:**

Species                                : Rabbit  
Result                                  : Mild skin irritation

**Betamethasone:**

Species                                : Rabbit  
Result                                  : Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Polyethylene glycol stearate:**

Species                                : Rabbit  
Result                                  : No eye irritation  
Method                                 : Draize Test

**Gentamicin:**

Species                                : Rabbit  
Result                                  : Mild eye irritation

**Betamethasone:**

Species                                : Rabbit  
Result                                  : No eye irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Polyethylene glycol stearate:**

Test Type                                : Open epicutaneous test  
Routes of exposure                     : Skin contact  
Species                                 : Guinea pig  
Result                                  : negative



**Gentamicin / Betamethasone Formulation**

Version 6.7      Revision Date: 07/22/2022      SDS Number: 434583-00019      Date of last issue: 04/09/2022  
Date of first issue: 01/06/2016

---

**Gentamicin:**

Remarks : No data available

**Betamethasone:**

Routes of exposure : Dermal  
Species : Guinea pig  
Result : Weak sensitizer

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Polyethylene glycol stearate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

**Gentamicin:**

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

Test Type: Chromosome aberration test in vitro  
Result: equivocal

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intravenous injection  
Result: negative

**Betamethasone:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

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

Test Type: Chromosome aberration test in vitro  
Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Oral  
Result: equivocal

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity**

Not classified based on available information.

## Gentamicin / Betamethasone Formulation

Version 6.7      Revision Date: 07/22/2022      SDS Number: 434583-00019      Date of last issue: 04/09/2022  
 Date of first issue: 01/06/2016

---

### Components:

#### **Gentamicin:**

Carcinogenicity - Assessment : No data available

#### **Reproductive toxicity**

May damage the unborn child.

### Components:

#### **Gentamicin:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
 Species: Rat  
 Fertility: NOAEL: 20 mg/kg body weight  
 Result: No significant adverse effects were reported

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rabbit  
 Developmental Toxicity: NOAEL: 3.6 mg/kg body weight  
 Result: No embryo-fetal toxicity.

Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Intraperitoneal  
 Developmental Toxicity: LOAEL: 75 mg/kg body weight  
 Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development  
 Species: Mouse  
 Application Route: Intraperitoneal  
 Developmental Toxicity: LOAEL: 10 mg/kg body weight  
 Result: Fetal mortality., No malformations were observed.

Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Intraperitoneal  
 Developmental Toxicity: LOAEL: 50 mg/kg body weight  
 Result: Fetal mortality., No malformations were observed.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

#### **Betamethasone:**

Effects on fetal development : Species: Rabbit  
 Application Route: Intramuscular  
 Developmental Toxicity: LOAEL: 0.05 mg/kg body weight  
 Result: Fetotoxicity., Malformations were observed.

Species: Rat  
 Application Route: Subcutaneous  
 Developmental Toxicity: LOAEL: 0.42 mg/kg body weight  
 Result: Malformations were observed.

Species: Mouse

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
6.7	07/22/2022	434583-00019	Date of first issue: 01/06/2016

---

Application Route: Intramuscular  
 Developmental Toxicity: LOAEL: 1 mg/kg body weight  
 Result: Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

### Components:

#### Gentamicin:

Target Organs : Kidney, inner ear  
 Assessment : Causes damage to organs through prolonged or repeated exposure.

#### Betamethasone:

Target Organs : Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland  
 Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Gentamicin:

Species : Dog  
 LOAEL : 3 mg/kg  
 Application Route : Intramuscular  
 Exposure time : 12 Months  
 Target Organs : Kidney  
 Symptoms : Vomiting, Salivation

Species : Monkey  
 LOAEL : 50 mg/kg  
 Application Route : Subcutaneous  
 Exposure time : 3 Weeks  
 Target Organs : Kidney, inner ear

Species : Monkey  
 LOAEL : 6 mg/kg  
 Application Route : Intramuscular  
 Exposure time : 3 Weeks  
 Target Organs : Blood, Kidney, inner ear, Liver

Species : Rat  
 NOAEL : 5 mg/kg  
 LOAEL : 10 mg/kg

**Gentamicin / Betamethasone Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 04/09/2022  
6.7                07/22/2022              434583-00019           Date of first issue: 01/06/2016

---

Application Route            : Intramuscular  
Exposure time                : 52 Weeks  
Target Organs                 : Kidney, Blood

Species                        : Rat  
NOAEL                         : 12.5 mg/kg  
LOAEL                         : 50 mg/kg  
Application Route            : Intramuscular  
Exposure time                : 13 Weeks  
Target Organs                 : Kidney

**Betamethasone:**

Species                        : Rabbit  
LOAEL                         : 0.05 %  
Application Route            : Skin contact  
Exposure time                : 10 - 30 d  
Target Organs                 : Pituitary gland, Immune system, muscle

Species                        : Rat  
LOAEL                         : 0.05 %  
Application Route            : Skin contact  
Exposure time                : 8 Weeks  
Target Organs                 : thymus gland

Species                        : Mouse  
LOAEL                         : 0.1 %  
Application Route            : Skin contact  
Exposure time                : 8 Weeks  
Target Organs                 : thymus gland

Species                        : Dog  
LOAEL                         : 0.05 mg/kg  
Application Route            : Oral  
Exposure time                : 28 d  
Target Organs                 : Blood, thymus gland, Adrenal gland

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Gentamicin:**

Ingestion                      : Target Organs: Kidney  
                                      : Target Organs: inner ear  
                                      : Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

**Betamethasone:**

Inhalation                      : Target Organs: Adrenal gland  
Skin contact                    : Symptoms: Redness, pruritis, Irritation

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
6.7	07/22/2022	434583-00019	Date of first issue: 01/06/2016

---

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Polyethylene glycol stearate:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l  
Exposure time: 96 h  
Method: DIN 38412

Toxicity to microorganisms : EC10 (Bacteria): > 10,000 mg/l  
Exposure time: 16 h

##### **Gentamicin:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 86 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

LC50 (Americamysis): 30 mg/l  
Exposure time: 96 h  
Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: 288.7 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

##### **Betamethasone:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Americamysis): > 50 mg/l  
Exposure time: 96 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

**Gentamicin / Betamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
6.7	07/22/2022	434583-00019	Date of first issue: 01/06/2016

---

Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l

Exposure time: 219 d

Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 8 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

**Persistence and degradability****Components:****Polyethylene glycol stearate:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: > 70 %  
Exposure time: 10 d  
Method: OECD Test Guideline 302B

**Gentamicin:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 100 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

**Bioaccumulative potential****Components:****Gentamicin:**

Partition coefficient: n-octanol/water : log Pow: < -2

**Betamethasone:**

Partition coefficient: n-octanol/water : log Pow: 2.11

**Mobility in soil**

No data available

**Other adverse effects**

No data available

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
6.7	07/22/2022	434583-00019	Date of first issue: 01/06/2016

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
 Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
 If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
 (Gentamicin, Benzalkonium chloride)  
 Class : 9  
 Packing group : III  
 Labels : 9

##### IATA-DGR

UN/ID No. : UN 3082  
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
 (Gentamicin, Benzalkonium chloride)  
 Class : 9  
 Packing group : III  
 Labels : Miscellaneous  
 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.  
 (Gentamicin, Benzalkonium chloride)  
 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.

#### Domestic regulation

##### TDG

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
 (Gentamicin, Benzalkonium chloride)  
 Class : 9

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
6.7	07/22/2022	434583-00019	Date of first issue: 01/06/2016

Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Gentamicin, Benzalkonium chloride)

### 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

### The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWA	:	Time-weighted average exposure value

AIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; KECl - 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect



**Gentamicin / Betamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
6.7	07/22/2022	434583-00019	Date of first issue: 01/06/2016

---

Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - 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; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 07/22/2022  
Date format : mm/dd/yyyy

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8