

**Gentamicin / Betamethasone Formulation**

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
Date of first issue: 06.01.2016

---

**Section 1: Identification**

Product name : Gentamicin / Betamethasone Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON)    0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

---

**Section 2: Hazard identification****GHS Classification**

Reproductive toxicity : Category 1

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

Hazardous to the aquatic environment - acute hazard : Category 1

Hazardous to the aquatic environment - chronic hazard : Category 1

**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.

## Gentamicin / Betamethasone Formulation

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
Date of first issue: 06.01.2016

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

**Prevention:**

P201 Obtain special instructions before use.  
P260 Do not breathe mist or vapours.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards which do not result in classification**

None known.

**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Polyethylene glycol stearate	9004-99-3	5
Gentamicin	1403-66-3	0.49
betamethasone	378-44-9	0.1
Benzalkonium chloride	8001-54-5	0.01

**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.

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
9.1	30.09.2023	434596-00022	Date of first issue: 06.01.2016

---

In case of eye contact	:	Thoroughly clean shoes before reuse. 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**

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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Hazchem Code	:	3Z

---

**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 dyking or other appropriate contain-

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
9.1	30.09.2023	434596-00022	Date of first issue: 06.01.2016

ment to keep material from spreading. If dyked 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.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
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.
- 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.
- Conditions for safe storage : Keep in properly labelled 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

---

**Section 8: Exposure controls/personal protection**
**Components with workplace control parameters**

Components	CAS-No.	Value type	Control parame-	Basis
------------	---------	------------	-----------------	-------

## Gentamicin / Betamethasone Formulation

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
 Date of first issue: 06.01.2016

		(Form of exposure)	ters / Permissible concentration	
Polyethylene glycol stearate	9004-99-3	WES-TWA	10 mg/m <sup>3</sup>	NZ 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 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.

**Section 9: Physical and chemical properties**

**Gentamicin / Betamethasone Formulation**

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
Date of first issue: 06.01.2016

---

Appearance : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

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

Vapour pressure : No data available

Relative vapour 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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

**Gentamicin / Betamethasone Formulation**

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
Date of first issue: 06.01.2016

---

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  
Hazardous decomposition products : No hazardous decomposition products are known.

---

**Section 11: Toxicological information**

Exposure routes : 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

**Gentamicin / Betamethasone Formulation**

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
Date of first issue: 06.01.2016

---

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

**Benzalkonium chloride:**

Acute oral toxicity : LD50 (Rat): 240 mg/kg  
Acute inhalation toxicity : LC50 (Rat, male): > 0.05 - 0.5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials  
Acute dermal toxicity : LD50 (Rat, female): 704 mg/kg

**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

**Benzalkonium chloride:**

Species : Human  
Result : Corrosive after 4 hours or less of exposure



**Gentamicin / Betamethasone Formulation**

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
Date of first issue: 06.01.2016

---

**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

**Benzalkonium chloride:**

Species : Rabbit  
Result : Irreversible effects on the eye

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

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

Test Type : Open epicutaneous test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

**Gentamicin:**

Remarks : No data available

**betamethasone:**

Exposure routes : Dermal  
Species : Guinea pig  
Result : Weak sensitizer

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
9.1	30.09.2023	434596-00022	Date of first issue: 06.01.2016

---

**Benzalkonium chloride:**

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Species	:	Humans
Result	:	negative

**Chronic toxicity****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.
-------------------------------------	---	--

**Benzalkonium chloride:**

**Gentamicin / Betamethasone Formulation**

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
Date of first issue: 06.01.2016

---

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
- Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:****Gentamicin:**

Carcinogenicity - Assessment : No data available

**Benzalkonium chloride:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : negative  
Remarks : Based on data from similar materials

Species : Mouse  
Application Route : Skin contact  
Exposure time : 80 weeks  
Result : negative

Species : Rabbit  
Application Route : Skin contact  
Exposure time : 90 weeks  
Result : negative

**Reproductive toxicity**

May damage the unborn child.

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
9.1	30.09.2023	434596-00022	Date of first issue: 06.01.2016

---

**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 foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight  
Result: No embryo-foetal toxicity

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

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

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

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

**betamethasone:**

Effects on foetal 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  
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.

**Gentamicin / Betamethasone Formulation**

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
Date of first issue: 06.01.2016

---

**Benzalkonium chloride:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative  
Remarks: Based on data from similar materials

**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.

**Benzalkonium chloride:**

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

**Repeated dose toxicity****Components:****Gentamicin:**

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

## Gentamicin / Betamethasone Formulation

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
 Date of first issue: 06.01.2016

---

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  
 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

**Gentamicin / Betamethasone Formulation**

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
Date of first issue: 06.01.2016

---

**Benzalkonium chloride:**

Species : Rat  
NOAEL :  $\geq 100$  mg/kg  
Application Route : Ingestion  
Exposure time : 12 Weeks

**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

---

**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  $\mu$ g/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
9.1	30.09.2023	434596-00022	Date of first issue: 06.01.2016

---

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

M-Factor (Acute aquatic toxicity) : 100  
 M-Factor (Chronic aquatic toxicity) : 1  
 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  
 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

M-Factor (Chronic aquatic toxicity) : 1,000



**Gentamicin / Betamethasone Formulation**

Version 9.1      Revision Date: 30.09.2023      SDS Number: 434596-00022      Date of last issue: 04.04.2023  
Date of first issue: 06.01.2016

---

**Benzalkonium chloride:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 0.28 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.0056 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Chlorella pyrenoidosa (algae)): 0.09 mg/l  
Exposure time: 72 h

M-Factor (Acute aquatic toxicity) : 100

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.032 mg/l  
Exposure time: 34 d

**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

**Benzalkonium chloride:**

Biodegradability : Result: Readily biodegradable.  
Method: OECD Test Guideline 301D  
Remarks: Based on data from similar materials

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

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

**betamethasone:**

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

**Benzalkonium chloride:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

**Gentamicin / Betamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
9.1	30.09.2023	434596-00022	Date of first issue: 06.01.2016

---

Bioconcentration factor (BCF): < 500  
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: 1.692  
Remarks: Calculation

**Mobility in soil**

No data available

**Other adverse effects**

No data available

---

**Section 13: Disposal considerations****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
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  
Environmentally hazardous : yes

**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 / Betamethasone Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
9.1	30.09.2023	434596-00022	Date of first issue: 06.01.2016

---

(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.

**National Regulations****NZS 5433**

UN number	: UN 3082
Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin, Benzalkonium chloride)
Class	: 9
Packing group	: III
Labels	: 9
Hazchem Code	: 3Z
Marine pollutant	: no

**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****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

not allocated

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

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

---

**Section 16: Other information**

Revision Date	: 30.09.2023
---------------	--------------

**Further information**

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

## Gentamicin / Betamethasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
9.1	30.09.2023	434596-00022	Date of first issue: 06.01.2016

---

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
 NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average  
 NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIIC - 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect 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

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.

NZ / EN