

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

### SECTION 1. IDENTIFICATION

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

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 37 McCarville Street  
Charlottetown, PE C1E 2A7  
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

Eye irritation : Category 2A  
Reproductive toxicity : Category 1B  
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

#### GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H319 Causes serious eye irritation.  
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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

and face protection.

### Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P337 + P313 If eye irritation persists: Get medical attention.

### 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./Unique ID	Concentration (% w/w)	Trade secret
Propylene glycol	1,2-Propanediol	57-55-6*	>= 10 - <= 30	TSC
Propan-2-ol	Isopropyl alcohol	67-63-0*	>= 10 - <= 30	TSC
Gentamicin	No data available	1403-66-3*	> 0 - <= 0.1	TSC
Betamethasone	No data available	378-44-9*	> 0 - <= 0.1	TSC

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

|| See Section 15 for HMIRA information.

## 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/13/2025
8.0	05/09/2026	5344768-00019	Date of first issue: 12/09/2019

- 
- |   |   |   |
|---|---|---|
| In case of eye contact                                      | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.          |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye irritation.<br>May damage the unborn child.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |
- 

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).   |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water. |
-

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

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.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapors.  
Do not swallow.  
Do not get in 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	Control parame-	Basis
------------	---------	------------	-----------------	-------

---

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
 Date of first issue: 12/09/2019

		(Form of exposure)	ters / Permissible concentration	
Propylene glycol	57-55-6	TWA (Vapour and aerosols)	50 ppm 155 mg/m <sup>3</sup>	CA ON OEL
		TWA (aerosol)	10 mg/m <sup>3</sup>	CA ON OEL
Propan-2-ol	67-63-0	STEL	400 ppm 984 mg/m <sup>3</sup>	CA AB OEL
		TWA	200 ppm 492 mg/m <sup>3</sup>	CA AB OEL
		TWA	200 ppm	CA BC OEL
		STEL	400 ppm	CA BC OEL
		TWAEV	200 ppm	CA QC OEL
		STEV	400 ppm	CA QC OEL
		TWA	200 ppm	ACGIH
		STEL	400 ppm	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

### Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work-week	40 mg/l	ACGIH BEI

**Engineering measures** : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable. 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/13/2025
8.0	05/09/2026	5344768-00019	Date of first issue: 12/09/2019

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 : Combined particulates and organic vapor 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
- Initial boiling point and boiling range : No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/13/2025
8.0	05/09/2026	5344768-00019	Date of first issue: 12/09/2019

---

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	:	Not applicable
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 characteristics Particle size	:	Not applicable

---

### 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/13/2025
8.0	05/09/2026	5344768-00019	Date of first issue: 12/09/2019

---

Incompatible materials	:	Oxidizing agents
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 oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

#### Components:

##### **Propylene glycol:**

Acute oral toxicity	:	LD50 (Rat): 22,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 44.9 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

##### **Propan-2-ol:**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 25 mg/l Exposure time: 6 h Test atmosphere: vapor
Acute dermal toxicity	:	LD50 (Rabbit): > 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	:	LD50 (Rat): 67 - 96 mg/kg

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

administration)      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

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **Propylene glycol:**

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

#### **Propan-2-ol:**

Species      :    Rabbit  
Result      :    No skin irritation

#### **Gentamicin:**

Species      :    Rabbit  
Result      :    Mild skin irritation

#### **Betamethasone:**

Species      :    Rabbit  
Result      :    Mild skin irritation

### **Serious eye damage/eye irritation**

Causes serious eye irritation.

### **Components:**

#### **Propylene glycol:**

Species      :    Rabbit  
Result      :    No eye irritation  
Method      :    OECD Test Guideline 405

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

### Propan-2-ol:

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

### 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:

#### Propylene glycol:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

#### Propan-2-ol:

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

#### 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:

#### Propylene glycol:

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

Result: negative

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

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

### Propan-2-ol:

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

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

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

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.

### **Components:**

#### **Propylene glycol:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

#### **Propan-2-ol:**

Species : Rat  
Application Route : inhalation (vapor)  
Exposure time : 104 weeks  
Method : OECD Test Guideline 451  
Result : negative

#### **Gentamicin:**

Carcinogenicity - Assessment : No data available

### **Reproductive toxicity**

May damage the unborn child.

### **Components:**

#### **Propylene glycol:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative  
Effects on fetal development : Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

#### **Propan-2-ol:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

	Result: negative
<b>Gentamicin:</b>	
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.
<b>Betamethasone:</b>	
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 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

||

### STOT-single exposure

Not classified based on available information.

### Components:

#### Propan-2-ol:

|| Assessment : May cause drowsiness or dizziness.

### 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:

#### Propylene glycol:

|| Species : Rat, male  
|| NOAEL : >= 1,700 mg/kg  
|| Application Route : Ingestion  
|| Exposure time : 2 y

#### Propan-2-ol:

|| Species : Rat  
|| NOAEL : 12.5 mg/l  
|| Application Route : inhalation (vapor)  
|| Exposure time : 104 Weeks

#### Gentamicin:

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

|| Species : Monkey

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

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

### **Aspiration toxicity**

Not classified based on available information.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

### 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:

##### **Propylene glycol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l  
Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l  
Exposure time: 18 h

##### **Propan-2-ol:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l  
Exposure time: 24 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 1,050 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

---

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

	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 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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

### Persistence and degradability

#### Components:

##### Propylene glycol:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

##### Propan-2-ol:

Biodegradability : Result: rapidly degradable  
BOD/COD : BOD: 1,19 (BOD5)  
COD: 2,23  
BOD/COD: 53 %

##### Gentamicin:

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

### Bioaccumulative potential

#### Components:

##### Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

##### Propan-2-ol:

Partition coefficient: n-octanol/water : log Pow: 0.05

##### 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

### Endocrine disrupting properties

No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

### 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.  
(betamethasone)

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.  
(Betamethasone)

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.  
(Betamethasone)

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,

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version 8.0      Revision Date: 05/09/2026      SDS Number: 5344768-00019      Date of last issue: 12/13/2025  
Date of first issue: 12/09/2019

---

N.O.S.  
(Betamethasone)  
Class : 9  
Packing group : III  
Labels : 9  
ERG Code : 171  
Marine pollutant : yes(Betamethasone)

### 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  
CA. DSL : not determined  
CN IECSC : not determined

### Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

---

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)  
CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)  
CA BC OEL : Canada. British Columbia OEL  
CA ON OEL : Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.  
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  
ACGIH / STEL : Short-term exposure limit  
CA AB OEL / TWA : 8-hour Occupational exposure limit  
CA AB OEL / STEL : 15-minute occupational exposure limit  
CA BC OEL / TWA : 8-hour time weighted average  
CA BC OEL / STEL : short-term exposure limit  
CA ON OEL / TWA : Time-Weighted Average Limit (TWA)  
CA QC OEL / TWA EV : Time-weighted average exposure value  
CA QC OEL / STEV : Short-term exposure value

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Betamethasone / Gentamicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/13/2025
8.0	05/09/2026	5344768-00019	Date of first issue: 12/09/2019

AIIC - 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 Standardization; 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; 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 : 05/09/2026  
Date format : mm/dd/yyyy

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 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