

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Betamethasone / Gentamicin Formulation

**Manufacturer or supplier's details**

Company name of supplier : MSD  
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@msd.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**

Serious eye damage/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/ face protection.

**Response:**

**Betamethasone / Gentamicin Formulation**

Version 7.0      Revision Date: 14.04.2025      SDS Number: 5344797-00013      Date of last issue: 04.12.2024  
Date of first issue: 09.12.2019

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 advice/attention.

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

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

None known.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	$\geq 10$ -< 20
Methyl p-Hydroxybenzoate	99-76-3	$\geq 1$ -< 5
Gentamicin	1403-66-3	< 0.1
Betamethasone	378-44-9	$\geq 0.01$ -< 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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.
- 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 : Causes serious eye irritation.  
May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

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 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

**Betamethasone / Gentamicin Formulation**

Version 7.0      Revision Date: 14.04.2025      SDS Number: 5344797-00013      Date of last issue: 04.12.2024  
Date of first issue: 09.12.2019

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.
- 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 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
Propan-2-ol	67-63-0	VLE-PPT	200 ppm	NOM-010-

## Betamethasone / Gentamicin Formulation

Version 7.0      Revision Date: 14.04.2025      SDS Number: 5344797-00013      Date of last issue: 04.12.2024  
 Date of first issue: 09.12.2019

				STPS-2014
		VLE-CT	400 ppm	NOM-010-STPS-2014
		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	MX BEI
		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. 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.

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

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.

**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
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

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

---

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

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**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.

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**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: > 5,000 mg/kg Method: Calculation method
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**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

**Components:****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

**Methyl p-Hydroxybenzoate:**

Acute oral toxicity	: LD50 (Rat, male): 2,100 mg/kg Method: OECD Test Guideline 401
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**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

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Propan-2-ol:**

Species	: Rabbit
Result	: No skin irritation

**Methyl p-Hydroxybenzoate:**



**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

---

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

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

**Methyl p-Hydroxybenzoate:**

Species	: Rabbit
Result	: No eye irritation

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

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

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

**Methyl p-Hydroxybenzoate:**

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

**Gentamicin:**

Remarks	: No data available
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**Betamethasone:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****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

**Methyl p-Hydroxybenzoate:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative  Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: positive
Genotoxicity in vivo	: Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Rat Application Route: Ingestion Method: OECD Test Guideline 478 Result: negative

**Gentamicin:**

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Result: negative
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**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

Genotoxicity in vivo	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
Genotoxicity in vivo	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.

**Components:****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
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**Reproductive toxicity**

May damage the unborn child.

**Components:****Propan-2-ol:**

Effects on fertility	: Test Type: Two-generation reproduction toxicity study
	Species: Rat
	Application Route: Ingestion

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Methyl p-Hydroxybenzoate:**

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Ingestion  
Result: negative

**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

## Betamethasone / Gentamicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

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.

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

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

**Methyl p-Hydroxybenzoate:**

Species : Rat  
NOAEL : 250 mg/kg  
LOAEL : 1,000 mg/kg  
Application Route : Ingestion  
Exposure time : 28 Days

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

|| Method : OECD Test Guideline 407

**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  
|| 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

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

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
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**Betamethasone:**

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

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****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

**Methyl p-Hydroxybenzoate:**

Toxicity to fish	: LC50 (Oryzias latipes (Japanese medaka)): 59.5 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 11.2 mg/l Exposure time: 48 h Method: ISO 6341
Toxicity to algae/aquatic plants	: ErC50 (Pseudokirchneriella subcapitata (green algae)): 91 mg/l Exposure time: 72 h Method: ISO 8692

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

EC10 (Pseudokirchneriella subcapitata (green algae)): 31 mg/l  
Exposure time: 72 h  
Method: ISO 8692

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 0.024 mg/l  
Exposure time: 70 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.2 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

**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  
Remarks: No toxicity at the limit of solubility.



## Betamethasone / Gentamicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

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

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

**Methyl p-Hydroxybenzoate:**

Biodegradability	: Result: Readily biodegradable. Biodegradation: 89 % Exposure time: 28 d Method: OECD Test Guideline 301B
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**Gentamicin:**

Biodegradability	: Result: rapidly degradable Biodegradation: 100 % Exposure time: 28 d Method: OECD Test Guideline 314
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**Bioaccumulative potential****Components:****Propan-2-ol:**

Partition coefficient: n-octanol/water	: log Pow: 0.05
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**Methyl p-Hydroxybenzoate:**

Partition coefficient: n-octanol/water	: log Pow: 1.98
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**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

**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

**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

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

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****NOM-002-SCT**

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

**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**

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

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

**SECTION 16. OTHER INFORMATION**

Revision Date	:	14.04.2025
Date format	:	dd.mm.yyyy

**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
MX BEI	:	Official Mexican Norm NOM-047-SSA1-2011, Environmental Health - Biological exposure indices for workers occupationally exposed to chemical agents
NOM-010-STPS-2014	:	Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Con-

**Betamethasone / Gentamicin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
7.0	14.04.2025	5344797-00013	Date of first issue: 09.12.2019

ACGIH / TWA : trol - Appendix 1 Occupational Exposure Limits  
ACGIH / STEL : 8-hour, time-weighted average  
NOM-010-STPS-2014 / VLE- : Short-term exposure limit  
PPT : Time weighted average limit value  
NOM-010-STPS-2014 / VLE- : Short term exposure limit value  
CT

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 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

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/>

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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