

Betamethasone / Gentamicin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 06.07.2024 5344771-00012 Date of first issue: 09.12.2019

SECTION 1. IDENTIFICATION

Product name : Betamethasone / Gentamicin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

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)

Short-term (acute) aquatic

hazard

Category 2

Long-term (chronic) aquatic

hazard

Category 1

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 sys-



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tem, muscle, thymus gland, Blood, Adrenal gland) through pro-

longed or repeated exposure. H401 Toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

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.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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 advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention.

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)
Propan-2-ol	67-63-0	>= 10 -< 20
Methyl p-Hydroxybenzoate	99-76-3	>= 1 -< 2,5
Gentamicin	1403-66-3	>= 0,025 -< 0,1
Betamethasone	378-44-9	>= 0,025 -< 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.



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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 contact, immediately flush eyes with plenty of water In case of eye contact

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.

First Aid responders should pay attention to self-protection, Protection of first-aiders

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 (CO2)

Drv chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Hazardous combustion prod-

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

cumstances 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, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Avoid release to the environment. Environmental precautions

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or



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oil barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

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	lo. Value type Control parame- Basis
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		(Form of exposure)	ters / Permissible concentration				
Propan-2-ol	67-63-0	CMP	400 ppm	AR OEL			
		CMP - CPT	500 ppm	AR OEL			
		TWA	200 ppm	ACGIH			
		STEL	400 ppm	ACGIH			
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB 2)	Internal			
	Further inforn	Further information: OTO					
Betamethasone	378-44-9	TWA	1 μg/m3 (OEB 4)	Internal			
	Further inforn	Further information: Skin					
		Wipe limit	10 μg/100 cm ²	Internal			

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling	Permissible concentra-	Basis
		·		time	tion	
Propan-2-ol	67-63-0	Acetone	Urine		2 mg/g creatinine	AR BEI
		Acetone	Urine	End of shift at end of work- week	40 mg/l	ACGIH BEI

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 : 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,



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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

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



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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. Can react with strong oxidizing agents.

Possibility of hazardous reac-

Conditions to avoid None known. 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 toxicity estimate: > 5.000 mg/kg Acute oral toxicity

Method: Calculation method

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



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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

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:

Species : Rabbit

Result : No skin irritation

Gentamicin:

Species : Rabbit

Result : Mild skin irritation



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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

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

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



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Betamethasone:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse Application Route: Oral Result: equivocal

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

Propan-2-ol:

Species : Rat

Application Route : inhalation (vapor)

Exposure time : 104 weeks

Method : OECD Test Guideline 451

Result : negative

Gentamicin:

Carcinogenicity - Assess-

ment

No data available

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

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



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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 - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.

Betamethasone:

Effects on fetal development : Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: LOAEL: 0,05 mg/kg body weight Result: Fetotoxicity., Malformations were observed.

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 0,42 mg/kg body weight

Result: Malformations were observed.

Species: Mouse

Application Route: Intramuscular

Developmental Toxicity: LOAEL: 1 mg/kg body weight

Result: Malformations were observed.

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.



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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: RatNOAEL: 250 mg/kgLOAEL: 1.000 mg/kgApplication Route: IngestionExposure time: 28 Days

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



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LOAEL 50 mg/kg Application Route Subcutaneous Exposure time 3 Weeks

Target Organs Kidney, inner ear

Species Monkey LOAEL 6 mg/kg LOAEL Application Route Intramuscular Exposure time 3 Weeks

Target Organs Blood, Kidney, inner ear, Liver

Species Rat NOAEL 5 mg/kg NOAEL : 5 mg/kg
LOAEL : 10 mg/kg
Application Route : Intramuscular
Exposure time : 52 Weeks
Target Organs : Kidney, Blood : Kidney, Blood Target Organs

: Rat

LOAEL
Application Route
Exposure time
Target Organs 12,5 mg/kg 50 mg/kg : Intramuscular 13 Weeks Target Organs Kidney

Species Rabbit LOAEL 0.05 % : Application Route Skin contact Exposure time 10 - 30 d

Target Organs Pituitary gland, Immune system, muscle

Species Rat : 0.05 % LOAEL 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 0,05 mg/kg LOAEL Application Route Oral

Exposure time 28 d

Target Organs Blood, thymus gland, Adrenal gland

Aspiration toxicity

Not classified based on available information.



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Experience with human exposure

Components:

Gentamicin:

Ingestion Target Organs: Kidney

Target Organs: inner ear

Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal

deafness

Betamethasone:

Target Organs: Adrenal gland Inhalation

Symptoms: Redness, pruritis, Irritation Skin contact

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

EC10 (Pseudokirchneriella subcapitata (green algae)): 31 mg/l

Exposure time: 72 h Method: ISO 8692

Toxicity to fish (Chronic tox-

icity)

NOEC (Danio rerio (zebra fish)): 0,024 mg/l

Exposure time: 70 d

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0,2 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211



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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

M-Factor (Acute aquatic tox-

M-Factor (Chronic aquatic

toxicity)

1

100

Toxicity to microorganisms EC50: 288,7 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Betamethasone:

aquatic invertebrates

Toxicity to daphnia and other : 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 tox-

city)

NOEC (Pimephales promelas (fathead minnow)): 0,052 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210



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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 (Chron-

ic 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

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

Gentamicin:

Biodegradability Result: rapidly degradable

> Biodegradation: 100 % Exposure time: 28 d

Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Propan-2-ol:

Partition coefficient: nlog Pow: 0,05

octanol/water

Methyl p-Hydroxybenzoate:

Partition coefficient: n-

log Pow: 1,98

octanol/water Gentamicin:

Partition coefficient: n-

 $\log Pow: < -2$

octanol/water

Betamethasone:

Partition coefficient: n-

octanol/water

log Pow: 2,11



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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.

Empty containers should be taken to an approved waste Contaminated packaging

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN 3082 **UN** number

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

(betamethasone)

Class 9 Ш Packing group Labels 9 Environmentally hazardous yes

IATA-DGR

UN 3082 UN/ID No.

Proper shipping name Environmentally hazardous substance, liquid, n.o.s.

(Betamethasone)

9 Class Ш Packing group

Miscellaneous Labels

Packing instruction (cargo 964

aircraft)

Packing instruction (passen-964

ger aircraft)

Environmentally hazardous yes

IMDG-Code

UN number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Betamethasone)

Class 9 Packing group Ш 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.



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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

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the : Propan-2-ol

preparation of drugs.

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 : 06.07.2024 Date format : dd.mm.yyyy

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD compile the Material Safety eChem Portal search results and European Chemicals Agen-

Data Sheet cy, 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.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
AR BEI : Argentina. Biological Exposure Indices
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit AR OEL / CMP : TLV (Threshold Limit Value) AR OEL / CMP - CPT : STEL (Short Term Limit Value)

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



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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; 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

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.

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