

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Betamethasone / Gentamicin Formulation

Version 6.0 Revision Date: 2025/04/14 SDS Number: 5344792-00015 Date of last issue: 2024/12/04
Date of first issue: 2019/12/09

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone / Gentamicin Formulation

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : liquid
Colour : No data available
Odour : No data available

Causes serious eye irritation. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

GHS Classification

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 1

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GHS label elements

Hazard pictograms	:	Three red diamond-shaped hazard pictograms. The first shows a person with a cracked skull, indicating serious eye irritation (H319). The second shows an exclamation mark, indicating danger (H360D). The third shows a dead tree and a dead fish, indicating toxic to aquatic life (H410).
Signal word	:	Danger
Hazard statements	:	<p>H319 Causes serious eye irritation. H360D May damage the unborn child. H372 Causes damage to organs through prolonged or repeated exposure. H401 Toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.</p>
Precautionary statements	:	<p>Prevention: P203 Obtain, read and follow all safety instructions before use. P260 Do not breathe mist or vapours. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.</p> <p>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. P318 IF exposed or concerned, get medical advice. P337 + P317 If eye irritation persists: Get medical help. P391 Collect spillage.</p> <p>Storage: P405 Store locked up.</p> <p>Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.</p>

Physical and chemical hazards

Not classified based on available information.

Health hazards

Causes serious eye irritation. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

Environmental hazards

Toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification

None known.

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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

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.

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.
Thoroughly clean shoes before reuse.

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.

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

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Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

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

7. HANDLING AND STORAGE

Handling

Technical measures : See Engineering measures under EXPOSURE

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Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
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.

Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propan-2-ol	67-63-0	PC-TWA	350 mg/m ³	CN OEL
		PC-STEL	700 mg/m ³	CN OEL
		TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
Gentamicin	1403-66-3	TWA	0.1 mg/m ³ (OEB 2)	Internal
			Further information: OTO	
	378-44-9	TWA	1 µg/m ³ (OEB 4)	Internal
		Further information: Skin		
		Wipe limit	10 µg/100 cm ²	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	40 mg/l	ACGIH

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				shift at end of work-week		BEI
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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.
Filter type	: Combined particulates and organic vapour type
Eye/face 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.
Hand protection	
Material	: Chemical-resistant gloves
Remarks	: Consider double gloving.
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work-

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ing 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-	:	Not applicable

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octanol/water
Auto-ignition 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

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.

11. TOXICOLOGICAL INFORMATION

Exposure routes : 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

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

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Test atmosphere: vapour

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

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Species	:	Rabbit
Result	:	Mild skin irritation

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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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Propan-2-ol:

Test Type	:	Buehler Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

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Methyl p-Hydroxybenzoate:

Test Type	:	Maurer optimisation test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

Gentamicin:

Remarks	:	No data available
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betamethasone:

Exposure routes	:	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

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Gentamicin:

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Result: negative
	Test Type: Chromosome aberration test in vitro Result: equivocal
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intravenous injection Result: negative

betamethasone:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Result: negative
	Test Type: Chromosome aberration test in vitro Result: positive
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Oral Result: equivocal
Germ cell mutagenicity - Assessment	: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

Propan-2-ol:

Species	: Rat
Application Route	: inhalation (vapour)
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 Result: negative
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

Methyl p-Hydroxybenzoate:

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

Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Rat Fertility: NOAEL: 20 mg/kg body weight Result: No significant adverse effects were reported
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rabbit Developmental Toxicity: NOAEL: 3.6 mg/kg body weight Result: No embryo-foetal toxicity
	: Test Type: Embryo-foetal development Species: Rat Application Route: Intraperitoneal Developmental Toxicity: LOAEL: 75 mg/kg body weight Result: Embryo-foetal toxicity
	: Test Type: Embryo-foetal development Species: Mouse Application Route: Intraperitoneal Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: foetal mortality, No malformations were observed.
	: Test Type: Embryo-foetal development Species: Rat Application Route: Intraperitoneal Developmental Toxicity: LOAEL: 50 mg/kg body weight Result: foetal mortality, No malformations were observed.

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

betamethasone:

Effects on foetal development

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

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

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

Reproductive toxicity - Assessment

: Clear evidence of adverse effects on development, based on animal experiments.

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 through prolonged or repeated exposure.

Components:

Gentamicin:

Target Organs
Assessment

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

betamethasone:

Target Organs
Assessment

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

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Repeated dose toxicity

Components:

Propan-2-ol:

Species	:	Rat
NOAEL	:	12.5 mg/l
Application Route	:	inhalation (vapour)
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
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

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||| Target Organs : Kidney

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

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

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

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Gentamicin:

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

betamethasone:

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propan-2-ol:

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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 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

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2025/04/14

SDS Number:
5344792-00015

Date of last issue: 2024/12/04
Date of first issue: 2019/12/09

Method: OECD Test Guideline 201

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

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

M-Factor (Acute aquatic toxicity) : 100

M-Factor (Chronic aquatic toxicity) : 1

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

betamethasone:

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

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

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

NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l
Exposure time: 219 d
Method: OECD Test Guideline 229

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

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

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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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Gentamicin:

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

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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.

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.

National Regulations

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GB 6944/12268

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(betamethasone)
Class : 9
Packing group : III
Labels : 9
Marine pollutant : no

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) : Not listed

Hazardous Chemicals for Priority Management under SAWs : Not listed

Catalogue of Specially Controlled Hazardous Chemicals : Not listed

List of Explosive Precursors : Not listed

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

Regulation on the Administration of Precursor Chemicals

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Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import and Export : Not listed
List of Controlled Ozone Depleting Substances : Not listed

Environmental Protection Law

List of Priority Controlled Chemicals : Not listed
List of Key Controlled New Pollutants : Not listed

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

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

16. OTHER INFORMATION

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Further information

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	: ACGIH - Biological Exposure Indices (BEI)
CN OEL	: Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
ACGIH / TWA	: 8-hour, time-weighted average
ACGIH / STEL	: Short-term exposure limit
CN OEL / PC-TWA	: Permissible concentration - time weighted average
CN OEL / PC-STEL	: Permissible concentration - short term exposure limit

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 -

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Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect 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

Disclaimer

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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