SAFETY DATA SHEET

Betamethasone / Gentamicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.0	06.07.2024	5344797-00011	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:

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	>= 10 -< 20
Methyl p-Hydroxybenzoate	99-76-3	>= 1 -< 5
Gentamicin	1403-66-3	< 0.1
Betamethasone	378-44-9	>= 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.

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 (CO2) 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 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-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/m3 (OEB 2)	Internal
	Further information: OTO			
Betamethasone	378-44-9	TWA	1 µg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm²	Internal

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam-pling time	Permissible concentra-tion	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 : 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, 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
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

Molecular weight	:	No data available
Particle characteristics		
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 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 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

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

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

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

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 - Assessment	:	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 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 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
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
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

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 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. 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

Gentamicin:

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

Bioaccumulative potential

Components:

Propan-2-ol:

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

Methyl p-Hydroxybenzoate:

Partition coefficient: n-octanol/water	:	log Pow: 1.98

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
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 : 06.07.2024
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 Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit value
NOM-010-STPS-2014 / VLE-CT : Short term exposure 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 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 con-

centration; 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

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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