

Gentamicin / Betamethasone Cream Formulation



Version 6.2

Revision Date: 30.09.2023

SDS Number: 1832924-00014

Date of last issue: 04.04.2023 Date of first issue: 13.07.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gentamicin / Betamethasone Cream Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : Rua Treze de Maio, 1161

Campinas, São Paulo, Brazil 13106-054

Telephone : +55 (19) 3758-2000

Emergency telephone : +55 (11) 3173-4931

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

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 in accordance with ABNT NBR 14725 Standard

Hazard pictograms :

*

Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.

H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through pro-

longed or repeated exposure. H401 Toxic to aquatic life.



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H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use. P264 Wash skin thoroughly after handling. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Other hazards which do not result in classification

None known.

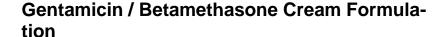
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Petrolatum	8009-03-8		>= 10 -< 20
Paraffin oil	8012-95-1	Aspiration hazard, Category 1 Long-term (chronic) aquatic hazard, Category 4	>= 5 -< 10
Alcohols, C16-18, ethoxylated	68439-49-6	Short-term (acute) aquatic hazard, Category 2	>= 1 -< 2,5
4-Chloro-3-methylphenol	59-50-7	Acute toxicity (Oral), Category 4 Skin corrosion, Category 1C Serious eye damage, Category 1 Skin sensitization, Sub-category 1B Specific target organ toxicity - single exposure, Category 3 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 3	>= 0,1 -< 0,25







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Gentamicin	1403-66-3	Reproductive toxicity, Category 1A Specific target organ toxicity - repeated exposure (Oral) (Kid- ney, inner ear), Cate- gory 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1 Category 1	>= 0,1 -< 0,25
Betamethasone	378-44-9	Acute toxicity (Inhalation), Category 2 Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland), Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 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.

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. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

In case of eye contact

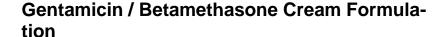
May damage the unborn child.

delayed

Causes damage to organs through prolonged or repeated

exposure.







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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

Vapors may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

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).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. 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

Sweep up or vacuum up spillage and collect in suitable

container for disposal.

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.



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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 dust, fume, gas, mist, vapors or spray.

Do not swallow.

Avoid contact with 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
Petrolatum	8009-03-8	TWA (Inhalable particulate matter)	5 mg/m³	ACGIH
Paraffin oil	8012-95-1	TWA (Inhalable particulate matter)	5 mg/m³	ACGIH
4-Chloro-3-methylphenol	59-50-7	TWA	200 μg/m3 (OEB 2)	Internal
		Wipe limit	100 μg/100 cm2	Internal





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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 cm ²	Internal

Engineering measures : Containment technologies suitable for controlling compounds

are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from

stationary container, ventilated enclosure, etc.).

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.

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. Combined particulates and organic vapor type

Filter type

Material

Hand protection

: 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 : cream

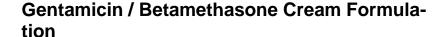
Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available





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Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : > 93,3 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not classified as a flammability hazard

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

: No data available

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 size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.



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Chemical stability

Possibility of hazardous reac-

tions

: Stable under normal conditions.

Vapors may form explosive mixture with air.

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

Skin contact Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Components:

Petrolatum:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Method: OECD Test Guideline 401

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Remarks: Based on data from similar materials

Paraffin oil:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

Alcohols, C16-18, ethoxylated:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:

Acute oral toxicity : LD50 (Mouse): 600 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 2,871 mg/l

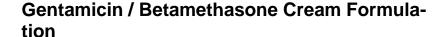
Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 5.000 mg/kg

Gentamicin:







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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:

Petrolatum:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Paraffin oil:

Species : Rabbit

Result : No skin irritation

Alcohols, C16-18, ethoxylated:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

4-Chloro-3-methylphenol:

Species : Rabbit

Method : OECD Test Guideline 404



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Result : Corrosive after 1 to 4 hours of exposure

Gentamicin:

Species : Rabbit

Result : Mild skin irritation

Betamethasone:

Species : Rabbit

Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Petrolatum:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Paraffin oil:

Species : Rabbit

Result : No eye irritation

Alcohols, C16-18, ethoxylated:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

4-Chloro-3-methylphenol:

Species : Rabbit

Result : Irreversible effects on the eye Method : OECD Test Guideline 405

Gentamicin:

Species : Rabbit

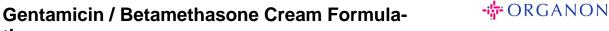
Result : Mild eye irritation

Betamethasone:

Species : Rabbit

Result : No eye irritation





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Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Petrolatum:

Test Type **Buehler Test** Skin contact Routes of exposure Species Guinea pig Result negative

Remarks Based on data from similar materials

Alcohols, C16-18, ethoxylated:

Test Type **Buehler Test** Routes of exposure Skin contact Species Guinea pig

Method OECD Test Guideline 406

Result negative

Based on data from similar materials Remarks

4-Chloro-3-methylphenol:

Test Type Maximization Test Skin contact Routes of exposure **Species** Guinea pig

Assessment Probability or evidence of low to moderate skin sensitization

rate in humans

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:

Petrolatum:

Genotoxicity in vitro Test Type: Chromosome aberration test in vitro

Result: negative

Remarks: Based on data from similar materials



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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials

Alcohols, C16-18, ethoxylated:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:

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

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



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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:

Petrolatum:

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

Gentamicin:

Carcinogenicity - Assess-

ment

No data available

Reproductive toxicity

May damage the unborn child.

Components:

Petrolatum:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Skin contact

Result: negative

Remarks: Based on data from similar materials

Alcohols, C16-18, ethoxylated:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Skin contact

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Skin contact



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Result: negative

Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

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



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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.

STOT-single exposure

Not classified based on available information.

Components:

4-Chloro-3-methylphenol:

Assessment : May cause respiratory irritation.

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:

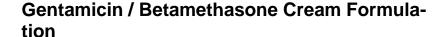
Petrolatum:

Species : Rat

NOAEL : 5.000 mg/kg
Application Route : Ingestion
Exposure time : 2 y

Paraffin oil:







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Species : Rat, female LOAEL : 161 mg/kg Application Route : Ingestion Exposure time : 90 Days

Alcohols, C16-18, ethoxylated:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Method : OECD Test Guideline 408

Remarks : Based on data from similar materials

4-Chloro-3-methylphenol:

Species : Rat
NOAEL : 200 mg/kg
LOAEL : 400 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

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

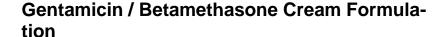
Application Route : Intramuscular

Exposure time : 52 Weeks

Target Organs : Kidney, Blood

Species : Rat
NOAEL : 12,5 mg/kg
LOAEL : 50 mg/kg
Application Route : Intramuscular







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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.

Components:

Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

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



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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Petrolatum:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10.000 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

NOEL (Pseudokirchneriella subcapitata (green algae)): >=

100 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates (Chronic toxicity)

NOEC (Daphnia magna (Water flea)): 10 mg/l

Exposure time: 21 d

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Paraffin oil:

Toxicity to fish : LL50 (Scophthalmus maximus (turbot)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Acartia tonsa (Calanoid copepod)): > 100 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Alcohols, C16-18, ethoxylated:







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Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 1 - 10 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 917 μg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,5 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Chlorella pyrenoidosa): 15 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Chlorella pyrenoidosa): 2,3 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0,32 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: 22,86 mg/l

Exposure time: 60 h

Gentamicin:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 86 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

LC50 (Americamysis): 30 mg/l

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







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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-

icity)

M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

1

100

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 tox-

icity)

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 (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:

Petrolatum:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 31 % Exposure time: 28 d



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Method: OECD Test Guideline 301F

Remarks: Based on data from similar materials

Alcohols, C16-18, ethoxylated:

Biodegradability : Result: Readily biodegradable.

Biodegradation: > 60 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 78 % Exposure time: 15 d

Method: OECD Test Guideline 301

Gentamicin:

Biodegradability : Result: rapidly degradable

Biodegradation: 100 % Exposure time: 28 d

Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Paraffin oil:

Partition coefficient: n- : log Pow: > 4

octanol/water Remarks: Calculation

Alcohols, C16-18, ethoxylated:

Bioaccumulation : Species: Fish

Bioconcentration factor (BCF): < 500

Remarks: Based on data from similar materials

Partition coefficient: n-

octanol/water

log Pow: > 4

4-Chloro-3-methylphenol:

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): 5,5 - 13

Partition coefficient: n-

octanol/water

: log Pow: 0,477

Gentamicin:

Partition coefficient: n-

: log Pow: < -2

octanol/water

Betamethasone:

Partition coefficient: n- : log Pow: 2,11



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octanol/water

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 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(betamethasone, Gentamicin)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Betamethasone, Gentamicin)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen: 956

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Betamethasone, Gentamicin)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes



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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

ANTT

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(betamethasone, Gentamicin)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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

National List of Carcinogenic Agents for Humans - :

(LINACH)

s - : Not applicable

Brazil. List of chemicals controlled by the Federal

Police

: 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 : 30.09.2023 Date format : dd.mm.yyyy

Further information

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 Agen-

cy, http://echa.europa.eu/

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)



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ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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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