

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Gentamicin / Posaconazole / Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.10	28.09.2024	1244613-00022	Date of first issue: 27.01.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Gentamicin / Posaconazole / Mometasone Suspension Formulation

Other means of identification : Mometamax Ultra Ear Drops Suspension for Dogs (91464)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1A	H360D: May damage the unborn child.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms :



Signal word : Danger

Hazard statements : H360D May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

Hazardous components which must be listed on the label:
Gentamicin

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Gentamicin	1403-66-3	Repr. 1A; H360D	>= 0,3 - < 1

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	215-765-8	STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1	
Posaconazole	171228-49-2	Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Adrenal gland, Bone marrow, Kid- ney, Liver, Nervous system, Reproduc- tive organs) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	$\geq 0,25 - < 1$
Mometasone	83919-23-7	Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 100	$\geq 0,1 - < 0,25$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

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- | | | |
|----------------------------|---|---|
| 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). |
| 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 | : | 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. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|------------------------------|
| Risks | : | May damage the unborn child. |
|-------|---|------------------------------|

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|--------------------------------|---|--|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing media | : | None known. |

5.2 Special hazards arising from the substance or mixture

- | | | |
|---------------------------------------|---|--|
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides |

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5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- 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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

- 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.

6.3 Methods and material for containment and cleaning up

- Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE

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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 vapours or spray mist.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
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.

7.2 Conditions for safe storage, including any incompatibilities

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

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Vapour)	50 mg/m3	FOR-2011-12-06-1358
		TWA (Mist and particles)	1 mg/m3	FOR-2011-12-06-1358

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Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB 2)	Internal
	Further information: OTO			
Posaconazole	171228-49-2	TWA	300 µg/m3 (OEB 2)	Internal
Mometasone	83919-23-7	TWA	1 µg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm ²	Internal

8.2 Exposure controls

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

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.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	suspension
Colour	:	white to off-white

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Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : 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

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : 0,874 g/cm³

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

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Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available
Molecular weight	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure :
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

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

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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

Posaconazole:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg
LD50 (Mouse): > 3.000 mg/kg

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

Mometasone:

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

Acute inhalation toxicity : LC50 (Rat): > 3,3 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: No mortality observed at this dose.

LC50 (Mouse): > 3,2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 300 mg/kg
Application Route: Subcutaneous
Symptoms: Breathing difficulties

Skin corrosion/irritation

Not classified based on available information.

Components:

Gentamicin:

Species : Rabbit
Result : Mild skin irritation

Posaconazole:

Species : Rabbit
Result : No skin irritation

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Mometasone:

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Gentamicin:

Species	:	Rabbit
Result	:	Mild eye irritation

Posaconazole:

Species	:	Rabbit
Result	:	Mild eye irritation

Mometasone:

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:

Gentamicin:

Remarks	:	No data available
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Posaconazole:

Test Type	:	Magnusson-Kligman-Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Mometasone:

Test Type	:	Maximisation Test
Exposure routes	:	Dermal
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitisation.
Result	:	negative
Remarks	:	The results of a test on guinea pigs showed this substance to

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be a weak skin sensitiser.

Germ cell mutagenicity

Not classified based on available information.

Components:

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

Posaconazole:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosomal aberration Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Intravenous Result: negative

Mometasone:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosomal aberration Test system: Chinese hamster lung cells Result: negative Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: Mouse Lymphoma Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse

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Application Route: Oral
Result: negative

Test Type: Chromosomal aberration
Species: Rat
Cell type: Bone marrow
Result: negative

Test Type: unscheduled DNA synthesis assay
Species: Rat
Cell type: Liver cells
Result: negative

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

Gentamicin:

Carcinogenicity - Assessment : No data available

Posaconazole:

Species : Rat
Application Route : oral (feed)
Exposure time : 2 Years
Result : positive
Remarks : The mechanism or mode of action is not relevant in humans.

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : positive
Remarks : The mechanism or mode of action is not relevant in humans.

Mometasone:

Species : Rat
Application Route : Inhalation
Exposure time : 2 Years
Dose : 0.067 mg/kg body weight
Result : negative

Species : Mouse
Application Route : Inhalation
Exposure time : 19 Months
Dose : 0.160 mg/kg body weight
Result : negative

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Reproductive toxicity

May damage the unborn child.

Components:

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

Posaconazole:

- | | | |
|-------------------------------|---|--|
| Effects on fertility | : | Test Type: Fertility/early embryonic development
Species: Rat, male
General Toxicity - Parent: NOAEL: 180 mg/kg body weight
Symptoms: No effects on mating performance
Result: negative |
| | | Test Type: Fertility/early embryonic development
Species: Rat, female
General Toxicity - Parent: NOAEL: 45 mg/kg body weight
Symptoms: No effects on mating performance
Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development |

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ment

Species: Rat, female
Application Route: Oral
Developmental Toxicity: LOAEL: 29 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Test Type: Embryo-foetal development
Species: Rabbit, female
Developmental Toxicity: LOAEL: 40 mg/kg body weight
Result: Fetotoxicity

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

Mometasone:

Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 0,015 mg/kg body weight
Symptoms: Reduced embryonic survival, Reduced foetal weight
Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Subcutaneous
Embryo-foetal toxicity: LOAEL: 0,06 mg/kg body weight
Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-foetal development
Species: Rat
Application Route: Dermal
Embryo-foetal toxicity: LOAEL: 0,3 mg/kg body weight
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Dermal
Embryo-foetal toxicity: LOAEL: 0,15 mg/kg body weight
Result: Embryo-foetal toxicity, Malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Subcutaneous
Embryo-foetal toxicity: LOAEL: 0,15 mg/kg body weight
Result: Effects on newborn

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 0,7 mg/kg body weight

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Result: Embryo-foetal toxicity, Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT - single exposure

Not classified based on available information.

Components:

Mometasone:

Remarks : Based on available data, the classification criteria are not met.

STOT - repeated exposure

Not classified based on available information.

Components:

Gentamicin:

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

Posaconazole:

Exposure routes : Ingestion
Target Organs : Adrenal gland, Bone marrow, Kidney, Liver, Reproductive organs, Nervous system
Assessment : Causes damage to organs through prolonged or repeated exposure.

Mometasone:

Exposure routes : inhalation (dust/mist/fume)
Target Organs : Immune system, Liver, Kidney, Skin
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Gentamicin:

Species : Dog
LOAEL : 3 mg/kg
Application Route : Intramuscular
Exposure time : 12 Months
Target Organs : Kidney
Symptoms : Vomiting, Salivation

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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

Posaconazole:

Species : Rat, female
LOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary

Species : Dog
LOAEL : 3 mg/kg
Application Route : Oral
Exposure time : 392 Days
Target Organs : Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue

Species : Monkey
LOAEL : 15 mg/kg
Application Route : Oral
Exposure time : 1 Months
Target Organs : Bone marrow, Adrenal gland, Lymph nodes, Blood

Species : Dog
LOAEL : 3 mg/kg
Application Route : Oral
Exposure time : 56 Weeks
Target Organs : Adrenal gland, Bone marrow, Kidney, Nervous system,

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spleen, thymus gland, Testis, lymphoid tissue

Species	: Monkey
LOAEL	: 180 mg/kg
Application Route	: Oral
Exposure time	: 12 Months
Target Organs	: Blood, Gastrointestinal tract, spleen

Species	: Monkey
LOAEL	: 8 mg/kg
Application Route	: Intravenous
Exposure time	: 1 Months
Target Organs	: Cardio-vascular system, Lungs, Adrenal gland, Blood

Mometasone:

Species	: Rat
NOAEL	: 0,005 mg/kg
LOAEL	: 0,3 mg/kg
Application Route	: Oral
Exposure time	: 30 d
Target Organs	: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species	: Dog
LOAEL	: 0,5 mg/kg
Application Route	: Oral
Exposure time	: 30 d
Target Organs	: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species	: Rat
NOAEL	: 0,00013 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 90 d
Target Organs	: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

Species	: Dog
NOAEL	: 0,0005 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 90 d
Target Organs	: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver

Aspiration toxicity

Not classified based on available information.

Components:

Mometasone:

Not applicable

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11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Gentamicin:

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

Posaconazole:

Ingestion : Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritis, Diarrhoea, hypertension, neutropenia, electrolyte imbalance

Mometasone:

Inhalation : Symptoms: allergic rhinitis, Headache, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion

Skin contact : Symptoms: Dermatitis, Itching

Further information

Components:

Mometasone:

Remarks : Dermal absorption possible

SECTION 12: Ecological information

12.1 Toxicity

Components:

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

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	Exposure time: 96 h Method: US-EPA OPPTS 850.1035
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 1,5 µg/l Exposure time: 72 h Method: OECD Test Guideline 201 EC50 (Anabaena flos-aquae (cyanobacterium)): 4,7 µg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Anabaena flos-aquae (cyanobacterium)): 1,6 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 100
Toxicity to microorganisms	: EC50 : 288,7 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
M-Factor (Chronic aquatic toxicity)	: 1
Posaconazole:	
Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,95 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0,276 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 0,509 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0,041 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic tox-	: 1

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icity)

Toxicity to microorganisms : EC50 (Natural microorganism): > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 0,206 mg/l
Exposure time: 33 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,244 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity) : 1

Mometasone:

Toxicity to fish : LC50 (Menidia beryllina (Silverside)): 0,11 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l
Exposure time: 7 d
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

EC50 (Americamysis): > 5 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 3,2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50 : > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

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NOEC : 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC: 0,00014 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,34 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity) : 100

12.2 Persistence and degradability

Components:

Gentamicin:

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

Posaconazole:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 28 h
Method: OECD Test Guideline 314

Stability in water : Degradation half life (DT50): > 30 d
Method: OECD Test Guideline 111

Mometasone:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Stability in water : Hydrolysis: 50 %(12 d)
Method: OECD Test Guideline 111

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12.3 Bioaccumulative potential

Components:

Gentamicin:

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

Posaconazole:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 20
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4,15

Mometasone:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107,1
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4,68

12.4 Mobility in soil

Components:

Posaconazole:

Distribution among environmental compartments : log Koc: 5,52

Mometasone:

Distribution among environmental compartments : log Koc: 4,02

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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

14.1 UN number or ID number

ADN	: UN 3082
ADR	: UN 3082
RID	: UN 3082
IMDG	: UN 3082
IATA	: UN 3082

14.2 UN proper shipping name

ADN	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Gentamicin)
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Gentamicin)
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Gentamicin)
IMDG	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Gentamicin)
IATA	: Environmentally hazardous substance, liquid, n.o.s. (Mometasone, Gentamicin)

14.3 Transport hazard class(es)

Class	Subsidiary risks
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ADN	:	9
ADR	:	9
RID	:	9
IMDG	:	9
IATA	:	9

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9

ADR	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)

RID	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9

IMDG	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F

IATA (Cargo)	
Packing instruction (cargo aircraft)	: 964
Packing instruction (LQ)	: Y964
Packing group	: III
Labels	: Miscellaneous

IATA (Passenger)	
Packing instruction (passenger aircraft)	: 964
Packing instruction (LQ)	: Y964
Packing group	: III
Labels	: Miscellaneous

14.5 Environmental hazards

ADN	
Environmentally hazardous	: yes

ADR	
Environmentally hazardous	: yes

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RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

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E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H319	: Causes serious eye irritation.
H360D	: May damage the unborn child.
H360Df	: May damage the unborn child. Suspected of damaging fertility.
H361d	: Suspected of damaging the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure if swallowed.
H373	: May cause damage to organs through prolonged or repeated exposure if inhaled.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Irrit.	: Eye irritation
Repr.	: Reproductive toxicity
STOT RE	: Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358	: Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	: Long term exposure limit

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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Classification of the mixture:

Repr. 1A	H360D
Aquatic Acute 1	H400
Aquatic Chronic 2	H411

Classification procedure:

Calculation method
Calculation method
Calculation method

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 mate-

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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.

NO / EN