

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

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

1.1 Product identifier

Trade name : Gentamicin / Betamethasone Formulation

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

Use of the Sub-stance/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. |
| Specific target organ toxicity - repeated exposure, Category 1 | H372: Causes damage to organs through prolonged or repeated exposure. |
| Short-term (acute) aquatic hazard, Category 1 | H400: Very toxic to aquatic life. |
| Long-term (chronic) aquatic hazard, Category 1 | H410: Very toxic to aquatic life with long lasting effects. |

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

Hazard statements : H360D May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
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 protection/ face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Gentamicin
betamethasone

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 | 1403-66-3 215-765-8 | Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; | 0,49 |

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

| | | | |
|-----------------------|-----------------------|--|------|
| | | H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1 | |
| betamethasone | 378-44-9 206-825-4 | Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Ad- renal gland) Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1.000 specific concentra- tion limit STOT RE 1; H372 >= 0,01 % Repr. 1B; H360D >= 0,01 % | 0,1 |
| Benzalkonium chloride | 8001-54-5 | Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Corr. 1; H314 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 2; H411 EUH071 M-Factor (Acute aquatic toxicity): 100 Acute toxicity esti- mate Acute oral toxicity: 240 mg/kg Acute inhalation toxicity (dust/mist): | 0,01 |

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

| | | | |
|--|--|---|--|
| | | 0,0501 mg/l Acute dermal toxicity: 704 mg/kg | |
|--|--|---|--|

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.
- 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.
Causes damage to organs through prolonged or repeated exposure.

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

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.1 | 30.09.2023 | 441402-00022 | Date of first issue: 06.01.2016 |

Carbon dioxide (CO₂)
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

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

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.1 | 30.09.2023 | 441402-00022 | Date of first issue: 06.01.2016 |

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 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 vapours. 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. |

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 |
|-----------------|---|-------------------|

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---------------------------|-----------|-------------------------------|-------------------------------|----------|
| Gentamicin | 1403-66-3 | TWA | 0.1 mg/m ³ (OEB 2) | Internal |
| Further information: OTO | | | | |
| betamethasone | 378-44-9 | TWA | 1 µg/m ³ (OEB 4) | Internal |
| Further information: Skin | | | | |
| | | Wipe limit | 10 µg/100 cm ² | Internal |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|-----------------------------------|-----------|-----------------|----------------------------|------------------------|
| Polyethylene glycol castor oil | Workers | Inhalation | Long-term systemic effects | 16,4 mg/m ³ |
| | Workers | Skin contact | Long-term systemic effects | 4,67 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 2,9 mg/m ³ |
| | Consumers | Skin contact | Long-term systemic effects | 1,67 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 1,67 mg/kg bw/day |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

| Substance name | Environmental Compartment | Value |
|--------------------------------|-----------------------------|---------------------------------|
| Polyethylene glycol castor oil | Fresh water | 0,000 mg/l |
| | Freshwater - intermittent | 0,0661 mg/l |
| | Marine water | 0,000 mg/l |
| | Marine water - intermittent | 0,00661 mg/l |
| | Fresh water sediment | 0,0129 mg/kg dry weight (d.w.) |
| | Marine sediment | 0,00129 mg/kg dry weight (d.w.) |
| | Soil | 0,00258 mg/kg dry weight (d.w.) |

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.

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.1 | 30.09.2023 | 441402-00022 | Date of first issue: 06.01.2016 |

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 143 |
| Filter type | : | Particulates type (P) |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | | |
|--|---|-------------------|
| Physical state | : | liquid |
| Colour | : | No data available |
| 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 | : | No data available |

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.1 | 30.09.2023 | 441402-00022 | Date of first issue: 06.01.2016 |

flammability limit

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 : No data available

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

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.

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.1 | 30.09.2023 | 441402-00022 | Date of first issue: 06.01.2016 |

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.

Product:

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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
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

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SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

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

Benzalkonium chloride:

Acute oral toxicity : LD50 (Rat): 240 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): > 0,05 - 0,5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat, female): 704 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Gentamicin:

Species : Rabbit
Result : Mild skin irritation

betamethasone:

Species : Rabbit
Result : Mild skin irritation

Benzalkonium chloride:

Species : Human
Result : Corrosive after 4 hours or less of exposure

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Gentamicin:

Species : Rabbit
Result : Mild eye irritation

betamethasone:

Species : Rabbit
Result : No eye irritation

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

Benzalkonium chloride:

Species : Rabbit
Result : Irreversible effects on the eye

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

betamethasone:

Exposure routes : Dermal
Species : Guinea pig
Result : Weak sensitizer

Benzalkonium chloride:

Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Species : Humans
Result : negative

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

betamethasone:

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

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

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.

Benzalkonium chloride:

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

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Gentamicin:

Carcinogenicity - Assessment : No data available

Benzalkonium chloride:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Method : OECD Test Guideline 453
Result : negative

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

Remarks : Based on data from similar materials

Species : Mouse
Application Route : Skin contact
Exposure time : 80 weeks
Result : negative

Species : Rabbit
Application Route : Skin contact
Exposure time : 90 weeks
Result : negative

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.

betamethasone:

Effects on foetal development : Species: Rabbit
Application Route: Intramuscular

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

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.

Benzalkonium chloride:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs 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.

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

Benzalkonium chloride:

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

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

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

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

Benzalkonium chloride:

Species : Rat
NOAEL : >= 100 mg/kg
Application Route : Ingestion
Exposure time : 12 Weeks

Aspiration toxicity

Not classified based on available information.

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

betamethasone:

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

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

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
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

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

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

- 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: 0,052 mg/l
Exposure time: 32 d
Species: *Pimephales promelas* (fathead minnow)
Method: OECD Test Guideline 210
- NOEC: 0,07 µg/l
Exposure time: 219 d
Species: *Oryzias latipes* (Japanese medaka)
Method: OECD Test Guideline 229
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 8 mg/l
Exposure time: 21 d
Species: *Daphnia magna* (Water flea)
Method: OECD Test Guideline 211
- M-Factor (Chronic aquatic toxicity) : 1.000
- Benzalkonium chloride:**
- Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): 0,28 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 0,0056 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (*Chlorella pyrenoidosa* (algae)): 0,09 mg/l
Exposure time: 72 h
- M-Factor (Acute aquatic toxicity) : 100
- Toxicity to fish (Chronic toxicity) : NOEC: 0,032 mg/l
Exposure time: 34 d
Species: *Pimephales promelas* (fathead minnow)

12.2 Persistence and degradability

Components:

Gentamicin:

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

Benzalkonium chloride:

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.1 | 30.09.2023 | 441402-00022 | Date of first issue: 06.01.2016 |

Biodegradability : Result: Readily biodegradable.
Method: OECD Test Guideline 301D
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

Gentamicin:

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

betamethasone:

Partition coefficient: n-octanol/water : log Pow: 2,11

Benzalkonium chloride:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): < 500
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: 1,692
Remarks: Calculation

12.4 Mobility in soil

No data available

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.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.1 | 30.09.2023 | 441402-00022 | Date of first issue: 06.01.2016 |

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

14.3 Transport hazard class(es)

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

14.4 Packing group

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

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

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

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 75, 3

If you intend to use this product as tattoo ink, please contact your vendor.

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) No 1005/2009 on substances that deplete the ozone layer : Not applicable

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

Regulation (EC) 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.

| | | Quantity 1 | Quantity 2 |
|----|-----------------------|------------|------------|
| E1 | ENVIRONMENTAL HAZARDS | 100 t | 200 t |

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

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.1 | 30.09.2023 | 441402-00022 | Date of first issue: 06.01.2016 |

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

| | | |
|--------|---|--|
| H301 | : | Toxic if swallowed. |
| H311 | : | Toxic in contact with skin. |
| H314 | : | Causes severe skin burns and eye damage. |
| H318 | : | Causes serious eye damage. |
| H330 | : | Fatal if inhaled. |
| H360D | : | May damage the unborn child. |
| H372 | : | Causes damage to organs through prolonged or repeated exposure. |
| H372 | : | Causes damage to organs through prolonged or repeated exposure if swallowed. |
| H400 | : | Very toxic to aquatic life. |
| H410 | : | Very toxic to aquatic life with long lasting effects. |
| H411 | : | Toxic to aquatic life with long lasting effects. |
| EUH071 | : | Corrosive to the respiratory tract. |

Full text of other abbreviations

| | | |
|-----------------|---|--|
| Acute Tox. | : | Acute toxicity |
| Aquatic Acute | : | Short-term (acute) aquatic hazard |
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard |
| Eye Dam. | : | Serious eye damage |
| Repr. | : | Reproductive toxicity |
| Skin Corr. | : | Skin corrosion |
| STOT RE | : | Specific target organ toxicity - repeated exposure |

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 La-

SAFETY DATA SHEET

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



Gentamicin / Betamethasone Formulation

Version 6.1 Revision Date: 30.09.2023 SDS Number: 441402-00022 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

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 |
| STOT RE 1 | H372 |
| Aquatic Acute 1 | H400 |
| Aquatic Chronic 1 | H410 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| 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 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