# SAFETY DATA SHEET

# Betamethasone / Gentamicin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
|---|---|---|---|
| 6.0 | 06.07.2024 | 5344802-00013 | Date of first issue: 09.12.2019 |

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

### 1.1 Product identifier

Trade name : Betamethasone / Gentamicin Formulation

### 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
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

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)**

| | |
|---|---|
| Eye irritation, Category 2 | H319: Causes serious eye irritation. |
| Reproductive toxicity, Category 1B | H360D: May damage the unborn child. |
| Specific target organ toxicity - repeated exposure, Category 1 | H372: Causes damage to organs through prolonged or repeated exposure. |
| 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

Hazard statements : H319 Causes serious eye irritation.
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.
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.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:

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.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

**Components**

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|
| Propan-2-ol | 67-63-0<br>200-661-7<br>603-117-00-0 | Flam. Liq. 2; H225<br>Eye Irrit. 2; H319<br>STOT SE 3; H336 | >= 10 - < 20 |
| Methyl p-Hydroxybenzoate | 99-76-3<br>202-785-7 | Aquatic Chronic 2; H411 | >= 1 - < 2,5 |
| Gentamicin | 1403-66-3<br>215-765-8 | Repr. 1A; H360D<br>STOT RE 1; H372 (Kidney, inner ear)<br>Aquatic Acute 1; H400<br>Aquatic Chronic 1; H410<br>M-Factor (Acute aquatic toxicity): 100<br>M-Factor (Chronic | >= 0,025 - < 0,1 |

| | | | |
|---|---|---|---|
| | | aquatic toxicity): 1 | |
| betamethasone | 378-44-9<br>206-825-4 | Acute Tox. 2; H330<br>Repr. 1B; H360D<br>STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)<br>Aquatic Chronic 1; H410<br>———————<br>M-Factor (Chronic aquatic toxicity): 1.000 | >= 0,025 - < 0,1 |

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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes serious eye irritation.
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
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 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.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 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 |
|---|---|---|---|---|
| Propan-2-ol | 67-63-0 | OEL-RL | 400 ppm | ZA OEL |
| | Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | |
| | | OEL- RL STEL/C | 800 ppm | ZA OEL |
| | Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | |
| Gentamicin | 1403-66-3 | TWA | 0.1 mg/m3 (OEB 2) | Internal |
| | Further information: OTO | | | |
| betamethasone | 378-44-9 | TWA | 1 µg/m3 (OEB 4) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 10 µg/100 cm² | Internal |

**Biological occupational exposure limits**

| Substance name | CAS-No. | Control parameters | Sampling time | Basis |
|---|---|---|---|---|
| Propan-2-ol | 67-63-0 | Acetone: 40 mg/l (Urine) | End of shift at end of workweek | ZA BEI |

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

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|---|---|---|---|---|
| Propylene glycol | Workers | Inhalation | Long-term local effects | 10 mg/m3 |
| | Workers | Inhalation | Long-term systemic effects | 168 mg/m3 |
| | Consumers | Inhalation | Long-term local effects | 10 mg/m3 |
| | Consumers | Inhalation | Long-term systemic effects | 50 mg/m3 |
| Propan-2-ol | Workers | Inhalation | Long-term systemic effects | 500 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 888 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 89 mg/m3 |
| | Consumers | Skin contact | Long-term systemic | 319 mg/kg |

| | | | | |
|---|---|---|---|---|
| | | | effects | bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 26 mg/kg bw/day |
| Methyl p-Hydroxybenzoate | Workers | Inhalation | Long-term systemic effects | 58,76 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 9,8 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 14,49 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 4,2 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 4,16 mg/kg bw/day |

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

| Substance name | Environmental Compartment | Value |
|---|---|---|
| Propylene glycol | Fresh water | 260 mg/l |
| | Freshwater - intermittent | 183 mg/l |
| | Marine water | 26 mg/l |
| | Sewage treatment plant | 20000 mg/l |
| | Fresh water sediment | 572 mg/kg dry weight (d.w.) |
| | Marine sediment | 57,2 mg/kg dry weight (d.w.) |
| | Soil | 50 mg/kg dry weight (d.w.) |
| Propan-2-ol | Fresh water | 140,9 mg/l |
| | Marine water | 140,9 mg/l |
| | Intermittent use/release | 140,9 mg/l |
| | Sewage treatment plant | 2251 mg/l |
| | Fresh water sediment | 552 mg/kg dry weight (d.w.) |
| | Marine sediment | 552 mg/kg dry weight (d.w.) |
| | Soil | 28 mg/kg dry weight (d.w.) |
| | Oral (Secondary Poisoning) | 160 mg/kg food |
| Methyl p-Hydroxybenzoate | Fresh water | 2,4 µg/l |
| | Freshwater - intermittent | 0,112 mg/l |
| | Marine water | 0,24 µg/l |
| | Sewage treatment plant | 2 mg/l |
| | Fresh water sediment | 0,0632 mg/kg dry weight (d.w.) |
| | Marine sediment | 0,00632 mg/kg dry weight (d.w.) |
| | Soil | 0,0115 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.
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.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>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. |
| 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

| | | |
|---|---|---|
| Appearance | : | liquid |
| Colour | : | No data available |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |

| | | |
|---|---|---|
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |

**9.2 Other information**

| | | |
|---|---|---|
| Flammability (liquids) | : | No data available |
| Molecular weight | : | No data available |
| Particle size | : | Not applicable |

## 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 toxicological effects

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

**Acute toxicity**

Not classified based on available information.

**Components:**

**Propan-2-ol:**

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

Acute inhalation toxicity : LC50 (Rat): > 25 mg/l
Exposure time: 6 h
Test atmosphere: vapour

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

**Methyl p-Hydroxybenzoate:**

Acute oral toxicity : LD50 (Rat, male): 2.100 mg/kg
Method: OECD Test Guideline 401

**Gentamicin:**

Acute oral toxicity : LD50 (Rat): 8.000 - 10.000 mg/kg

LD50 (Mouse): 10.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0,2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg
Application Route: Intravenous

LD50 (Rat): 371 - 384 mg/kg
Application Route: Intramuscular

LDLo (Monkey): 30 mg/kg
Application Route: Intravenous

**betamethasone:**

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

LD50 (Mouse): > 4.500 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0,4 mg/l
Exposure time: 4 h

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Propan-2-ol:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No skin irritation |

**Methyl p-Hydroxybenzoate:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No skin irritation |

**Gentamicin:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild skin irritation |

**betamethasone:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild skin irritation |

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:**

**Propan-2-ol:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Irritation to eyes, reversing within 21 days |

**Methyl p-Hydroxybenzoate:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No eye irritation |

**Gentamicin:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

**betamethasone:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No eye irritation |

**Respiratory or skin sensitisation**

**Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Propan-2-ol:**

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

**Methyl p-Hydroxybenzoate:**

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

**Gentamicin:**

| | | |
|---|---|---|
| Remarks | : | No data available |

**betamethasone:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Propan-2-ol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative |

**Methyl p-Hydroxybenzoate:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473 |

Result: positive

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 478
Result: negative

**Gentamicin:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: equivocal

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intravenous injection
Result: negative

**betamethasone:**

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Oral
Result: equivocal

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

**Carcinogenicity**

Not classified based on available information.

**Components:**

**Propan-2-ol:**

Species : Rat
Application Route : inhalation (vapour)
Exposure time : 104 weeks
Method : OECD Test Guideline 451
Result : negative

**Gentamicin:**

Carcinogenicity - Assessment : No data available

**Reproductive toxicity**

May damage the unborn child.

**Components:**

**Propan-2-ol:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

**Methyl p-Hydroxybenzoate:**

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

**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<br>Application Route: Intramuscular<br>Developmental Toxicity: LOAEL: 0,05 mg/kg body weight<br>Result: Fetotoxicity, Malformations were observed.<br><br>Species: Rat<br>Application Route: Subcutaneous<br>Developmental Toxicity: LOAEL: 0,42 mg/kg body weight<br>Result: Malformations were observed.<br><br>Species: Mouse<br>Application Route: Intramuscular<br>Developmental Toxicity: LOAEL: 1 mg/kg body weight<br>Result: Malformations were observed. |
| Reproductive toxicity - Assessment | : | Clear evidence of adverse effects on development, based on animal experiments. |

**STOT - single exposure**

Not classified based on available information.

**Components:**

**Propan-2-ol:**

| | | |
|---|---|---|
| Assessment | : | May cause drowsiness or dizziness. |

**STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

**Components:**

**Gentamicin:**

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

**betamethasone:**

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

**Repeated dose toxicity**

**Components:**

**Propan-2-ol:**

| | | |
|---|---|---|
| Species | : | Rat |

| | | |
|---|---|---|
| NOAEL | : | 12,5 mg/l |
| Application Route | : | inhalation (vapour) |
| Exposure time | : | 104 Weeks |

**Methyl p-Hydroxybenzoate:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 250 mg/kg |
| LOAEL | : | 1.000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 28 Days |
| Method | : | OECD Test Guideline 407 |

**Gentamicin:**

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

| | | |
|---|---|---|
| Species | : | Monkey |
| LOAEL | : | 50 mg/kg |
| Application Route | : | Subcutaneous |
| Exposure time | : | 3 Weeks |
| Target Organs | : | Kidney, inner ear |

| | | |
|---|---|---|
| Species | : | Monkey |
| LOAEL | : | 6 mg/kg |
| Application Route | : | Intramuscular |
| Exposure time | : | 3 Weeks |
| Target Organs | : | Blood, Kidney, inner ear, Liver |

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 5 mg/kg |
| LOAEL | : | 10 mg/kg |
| Application Route | : | Intramuscular |
| Exposure time | : | 52 Weeks |
| Target Organs | : | Kidney, Blood |

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 12,5 mg/kg |
| LOAEL | : | 50 mg/kg |
| Application Route | : | Intramuscular |
| Exposure time | : | 13 Weeks |
| Target Organs | : | Kidney |

**betamethasone:**

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

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

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

| | | |
|---|---|---|
| Species | : | Dog |
| LOAEL | : | 0,05 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 28 d |
| Target Organs | : | Blood, thymus gland, Adrenal gland |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Gentamicin:**

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

**betamethasone:**

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

## SECTION 12: Ecological information

### 12.1 Toxicity

**Components:**

**Propan-2-ol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 9.640 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 10.000 mg/l<br>Exposure time: 24 h |
| Toxicity to microorganisms | : | EC50 (Pseudomonas putida): > 1.050 mg/l<br>Exposure time: 16 h |

**Methyl p-Hydroxybenzoate:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oryzias latipes (Japanese medaka)): 59,5 mg/l<br>Exposure time: 96 h |

Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 11,2 mg/l
Exposure time: 48 h
Method: ISO 6341

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 91 mg/l
Exposure time: 72 h
Method: ISO 8692

EC10 (Pseudokirchneriella subcapitata (green algae)): 31 mg/l
Exposure time: 72 h
Method: ISO 8692

Toxicity to fish (Chronic toxicity) : NOEC: 0,024 mg/l
Exposure time: 70 d
Species: Danio rerio (zebra fish)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,2 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

**Gentamicin:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 86 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

LC50 (Americamysis): 30 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1,5 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 4,7 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1,6 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

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

### 12.2 Persistence and degradability

**Components:**

**Propan-2-ol:**

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1,19 (BOD5)
COD: 2,23
BOD/COD: 53 %

**Methyl p-Hydroxybenzoate:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 89 %

Exposure time: 28 d
Method: OECD Test Guideline 301B

**Gentamicin:**

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

### 12.3 Bioaccumulative potential

**Components:**

**Propan-2-ol:**

Partition coefficient: n-octanol/water : log Pow: 0,05

**Methyl p-Hydroxybenzoate:**

Partition coefficient: n-octanol/water : log Pow: 1,98

**Gentamicin:**

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

**betamethasone:**

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

### 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 Other adverse effects

**Product:**

Endocrine disrupting potential : 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 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.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14: Transport information

### 14.1 UN 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.<br>(betamethasone) |
| **ADR** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(betamethasone) |
| **RID** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(betamethasone) |
| **IMDG** | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(betamethasone) |
| **IATA** | : | Environmentally hazardous substance, liquid, n.o.s.<br>(betamethasone) |

### 14.3 Transport hazard class(es)

| | | Class | Subsidiary risks |
|---|---|---|---|
| **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

**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 Transport in bulk according to Annex II of Marpol and the IBC Code**

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**

**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**

H225 : Highly flammable liquid and vapour.
H319 : Causes serious eye irritation.
H330 : Fatal if inhaled.
H336 : May cause drowsiness or dizziness.
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.

**Full text of other abbreviations**

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
ZA BEI : South Africa. The Regulations for Hazardous Chemical Agents, Biological Exposure Indices
ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour expo-

sure or equivalent (12 hour shifts)

ZA OEL / OEL- RL STEL/C : Occupational Exposure Limit Restricted limit - Short term occupational exposure limits / ceiling limits

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:** | | **Classification procedure:** |
|---|---|---|
| Eye Irrit. 2 | H319 | Calculation method |
| Repr. 1B | H360D | Calculation method |
| STOT RE 1 | H372 | Calculation method |
| Aquatic Chronic 1 | H410 | Calculation method |

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

ZA / EN