# SAFETY DATA SHEET

## Betamethasone / Gentamicin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
|---|---|---|---|
| 4.0 | 06.07.2024 | 5344770-00011 | Date of first issue: 09.12.2019 |

## SECTION 1: IDENTIFICATION

Product name : Betamethasone / Gentamicin Formulation

**Manufacturer or supplier's details**

Company : Intervet Australia Pty Limited (trading as MSD Animal Health)

Address : 91-105 Harpin Street
Bendigo 3550, Victoria Austrailia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product
Restrictions on use : Not applicable

## SECTION 2. HAZARDS IDENTIFICATION

**GHS Classification**

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

**GHS label elements**

Hazard pictograms :

Signal word : Danger

Hazard statements : H319 Causes serious eye irritation.
H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| Propylene glycol | 57-55-6 | >= 10 -< 30 |
| Propan-2-ol | 67-63-0 | >= 10 -< 20 |
| Gentamicin | 1403-66-3 | < 0.3 |
| betamethasone | 378-44-9 | >= 0.01 -< 0.3 |

## SECTION 4. FIRST AID MEASURES

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

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.

| | | |
|---|---|---|
| | | Thoroughly clean shoes before reuse. |
| In case of eye contact | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye irritation.<br>May damage the unborn child.<br>Causes damage to organs through prolonged or repeated exposure. |
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician | : | Treat symptomatically and supportively. |

## SECTION 5. FIREFIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |
| Hazchem Code | : | •3Z |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained. |

| | | |
|---|---|---|
| Methods and materials for containment and cleaning up | : | Soak up with inert absorbent material.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

## SECTION 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents |

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| Propylene glycol | 57-55-6 | TWA (particulate) | 10 mg/m3 | AU OEL |
| | | TWA (Total (vapour and particles)) | 150 ppm<br>474 mg/m3 | AU OEL |
| Propan-2-ol | 67-63-0 | STEL | 500 ppm<br>1,230 mg/m3 | AU OEL |
| | | TWA | 400 ppm<br>983 mg/m3 | AU OEL |
| | | TWA | 200 ppm | ACGIH |
| | | STEL | 400 ppm | ACGIH |
| Gentamicin | 1403-66-3 | TWA | 0.1 mg/m3 (OEB 2) | Internal |
| | Further information: OTO | | | |
| betamethasone | 378-44-9 | TWA | 1 µg/m3 (OEB 4) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 10 µg/100 cm² | Internal |

**Biological occupational exposure limits**

| Components | CAS-No. | Control parameters | Biological specimen | Sampling time | Permissible concentration | Basis |
|---|---|---|---|---|---|---|
| Propan-2-ol | 67-63-0 | Acetone | Urine | End of shift at end of work-week | 40 mg/l | ACGIH BEI |

**Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Essentially no open handling permitted.
Use closed processing systems or containment technologies.
If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Hand protection

| | | |
|---|---|---|
| Material | : | Chemical-resistant gloves |
| Remarks | : | Consider double gloving. |
| Eye 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. |
| 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. |

## SECTION 9. 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 |
| Flammability (liquids) | : | No data available |
| 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. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| Particle size | : | Not applicable |

## SECTION 10. STABILITY AND REACTIVITY

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

## SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 22,000 mg/kg |

| | | |
|---|---|---|
| Acute inhalation toxicity | : | LC50 (Rat): > 44.9 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg<br>Assessment: The substance or mixture has no acute dermal toxicity |

**Propan-2-ol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 25 mg/l<br>Exposure time: 6 h<br>Test atmosphere: vapour |
| Acute dermal toxicity | : | LD50 (Rabbit): > 5,000 mg/kg |

**Gentamicin:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 8,000 - 10,000 mg/kg<br><br>LD50 (Mouse): 10,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 0.2 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Remarks: No mortality observed at this dose. |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 67 - 96 mg/kg<br>Application Route: Intravenous<br><br>LD50 (Rat): 371 - 384 mg/kg<br>Application Route: Intramuscular<br><br>LDLo (Monkey): 30 mg/kg<br>Application Route: Intravenous |

**betamethasone:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg<br><br>LD50 (Mouse): > 4,500 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): 0.4 mg/l<br>Exposure time: 4 h |

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 404 |
| Result | : | No skin irritation |

**Propan-2-ol:**

| | | |
|---|---|---|
| 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:**

**Propylene glycol:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No eye irritation |
| Method | : | OECD Test Guideline 405 |

**Propan-2-ol:**

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

**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:**

**Propylene glycol:**

| | | |
|---|---|---|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Result | : | negative |

**Propan-2-ol:**

| | | |
|---|---|---|
| Test Type | : | Buehler 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 |

**Chronic toxicity**

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Propylene glycol:**

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

**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 |

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

**Gentamicin:**

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

**betamethasone:**

| | | |
|---|---|---|
| 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<br><br>Test Type: Chromosome aberration test in vitro<br>Result: positive |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Oral<br>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:**

**Propylene glycol:**

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

**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:**

**Propylene glycol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Propan-2-ol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Gentamicin:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Fertility: NOAEL: 20 mg/kg body weight<br>Result: No significant adverse effects were reported |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Developmental Toxicity: NOAEL: 3.6 mg/kg body weight<br>Result: No embryo-foetal toxicity<br><br>Test Type: Embryo-foetal development<br>Species: Rat |

| | | |
|---|---|---|
| | | Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 75 mg/kg body weight<br>Result: Embryo-foetal toxicity<br><br>Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 10 mg/kg body weight<br>Result: foetal mortality, No malformations were observed.<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 50 mg/kg body weight<br>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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

**Components:**

**Gentamicin:**

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

**betamethasone:**

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

**Repeated dose toxicity**

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Species | : | Rat, male |
| NOAEL | : | >= 1,700 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 2 yr |

**Propan-2-ol:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 12.5 mg/l |
| Application Route | : | inhalation (vapour) |
| Exposure time | : | 104 Weeks |

**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

**Ecotoxicity**

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l<br>Exposure time: 7 d |
| Toxicity to microorganisms | : | NOEC (Pseudomonas putida): > 20,000 mg/l<br>Exposure time: 18 h |

**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 |

**Gentamicin:**

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 86 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br><br>LC50 (Americamysis): 30 mg/l<br>Exposure time: 96 h<br>Method: US-EPA OPPTS 850.1035 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l |

| | | |
|---|---|---|
| | | Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to microorganisms | : | EC50: 288.7 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |

**betamethasone:**

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Americamysis): > 50 mg/l<br>Exposure time: 96 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210<br><br>NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l<br>Exposure time: 219 d<br>Method: OECD Test Guideline 229 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 8 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211 |

**Persistence and degradability**

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 98.3 % |

| | | |
|---|---|---|
| | | Exposure time: 28 d<br>Method: OECD Test Guideline 301F |

**Propan-2-ol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: rapidly degradable |
| BOD/COD | : | BOD: 1,19 (BOD5)<br>COD: 2,23<br>BOD/COD: 53 % |

**Gentamicin:**

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

**Bioaccumulative potential**

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: -1.07<br>Method: Regulation (EC) No. 440/2008, Annex, A.8 |

**Propan-2-ol:**

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

**Gentamicin:**

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

**betamethasone:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: 2.11 |

**Mobility in soil**

No data available

**Other adverse effects**

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations. |
| 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

### International Regulations

**UNRTDG**

| | | |
|---|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Environmentally hazardous | : | yes |

**IATA-DGR**

| | | |
|---|---|---|
| UN/ID No. | : | UN 3082 |
| Proper shipping name | : | Environmentally hazardous substance, liquid, n.o.s. (betamethasone) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | Miscellaneous |
| Packing instruction (cargo aircraft) | : | 964 |
| Packing instruction (passenger aircraft) | : | 964 |
| Environmentally hazardous | : | yes |

**IMDG-Code**

| | | |
|---|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| EmS Code | : | F-A, S-F |
| Marine pollutant | : | yes |

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

Not applicable for product as supplied.

### National Regulations

**ADG**

| | | |
|---|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Hazchem Code | : | •3Z |
| Environmentally hazardous | : | yes |

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

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

| | | |
|---|---|---|
| Therapeutic Goods (Poisons Standard) Instrument | : | No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical) |
| Prohibition/Licensing Requirements | : | There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations. |

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

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

## SECTION 16: ANY OTHER RELEVANT INFORMATION

**Further information**

| | | |
|---|---|---|
| Revision Date | : | 06.07.2024 |
| 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/ |

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

| | | |
|---|---|---|
| Date format | : | dd.mm.yyyy |

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| ACGIH BEI | : | ACGIH - Biological Exposure Indices (BEI) |
| AU OEL | : | Australia. Workplace Exposure Standards for Airborne Contaminants. |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| ACGIH / STEL | : | Short-term exposure limit |
| AU OEL / TWA | : | Exposure standard - time weighted average |

AU OEL / STEL : Exposure standard - short term exposure limit

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

AU / EN