

Dexamethasone / Trichlormethiazide Formulation

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| Version | Revision Date: | SDS Number: | Date of last issue: 14.04.2025 |
| 5.1 | 20.06.2025 | 5408269-00015 | Date of first issue: 13.02.2020 |

SECTION 1: IDENTIFICATION

Product name : Dexamethasone / Trichlormethiazide Formulation

Manufacturer or supplier's details

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

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

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

Skin sensitisation : Category 1

Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms :  

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H360D May damage the unborn child.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.

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P261 Avoid breathing mist or vapours.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
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.
P333 + P313 If skin irritation or rash occurs: 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 | ≥ 60 - ≤ 100 |
| N,N-Dimethylacetamide | 127-19-5 | ≥ 10 - < 30 |
| Benzyl alcohol | 100-51-6 | ≥ 1 - < 10 |
| Trichlormethiazide | 133-67-5 | < 10 |
| dexamethasone | 50-02-2 | < 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 |

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| | | 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. |
| Most important symptoms and effects, both acute and delayed | : | May cause an allergic skin reaction. Causes serious eye irritation. May damage the unborn child. |
| 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 Alcohol-resistant foam Carbon dioxide (CO ₂) 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 Nitrogen oxides (NO _x) |
| 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. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

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| Personal precautions, protective equipment and emergency measures | : | Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- |
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SECTION 7. HANDLING AND STORAGE

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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.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

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/m ³ | AU OEL |
| | | TWA (Total (vapour and particles)) | 150 ppm 474 mg/m ³ | AU OEL |
| N,N-Dimethylacetamide | 127-19-5 | TWA | 10 ppm 36 mg/m ³ | AU OEL |
| Further information: Skin absorption | | | | |
| | | TWA | 10 ppm | ACGIH |
| Trichlormethiazide | 133-67-5 | TWA | 1 µg/m ³ (OEB4) | Internal |
| | | Wipe limit | 10 µg/100 cm ² | Internal |
| dexamethasone | 50-02-2 | TWA | 10 µg/m ³ (OEB 3) | Internal |
| Further information: Skin | | | | |
| | | Wipe limit | 100 µg/100 cm ² | Internal |

Biological occupational exposure limits

| Components | CAS-No. | Control parameters | Biological specimen | Sampling time | Permissible concentration | Basis |
|-----------------------|----------|--------------------|---------------------|----------------------------------|---------------------------|-----------|
| N,N-Dimethylacetamide | 127-19-5 | N-Methylacetamide | Urine | End of shift at end of work-week | 30 mg/g creatinine | ACGIH BEI |

Engineering measures : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If

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applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

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. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection | : | Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing. |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|-----------------|---|-------------------|
| Appearance | : | liquid |
| Colour | : | colourless |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| pH | : | No data available |

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| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | 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 |

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SECTION 10. STABILITY AND REACTIVITY

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| 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.

Product:

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|---------------------|---|--|
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method |
|---------------------|---|--|

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

| | | |
|-----------------------|---|--|
| Acute dermal toxicity | : | Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method |
|-----------------------|---|--|

Components:**Propylene glycol:**

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

| | | |
|---------------------------|---|---|
| Acute inhalation toxicity | : | LC50 (Rat): > 44.9 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
|---------------------------|---|---|

| | | |
|-----------------------|---|---|
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity |
|-----------------------|---|---|

N,N-Dimethylacetamide:

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|---------------------|---|-------------------------|
| Acute oral toxicity | : | LD50 (Rat): 4,800 mg/kg |
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| Acute inhalation toxicity | : | LC50 (Rat): 2.2 mg/l |
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Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : Acute toxicity estimate: 1,100 mg/kg
Method: Expert judgement
Remarks: Based on national or regional regulation.

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

Trichlormethiazide:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Symptoms: hyperglycemia

LD50 (Mouse): 2,600 mg/kg

dexamethasone:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

LD50 (Mouse): > 6,500 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 14 mg/kg
Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

Components:**Propylene glycol:**

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

N,N-Dimethylacetamide:

Species : Rabbit
Result : No skin irritation

Benzyl alcohol:

Species : Rabbit

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Method : OECD Test Guideline 404
Result : No skin irritation

dexamethasone:

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

N,N-Dimethylacetamide:

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

Benzyl alcohol:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

dexamethasone:

Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:**Propylene glycol:**

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

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N,N-Dimethylacetamide:

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

Benzyl alcohol:

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

| | |
|------------|--|
| Assessment | : Probability or evidence of low to moderate skin sensitisation rate in humans |
|------------|--|

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**Propylene glycol:**

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

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

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

N,N-Dimethylacetamide:

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

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

Benzyl alcohol:

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

dexamethasone:

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

Test Type: in vitro assay
Test system: mouse lymphoma cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Propylene glycol:**

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

N,N-Dimethylacetamide:

Species : Rat
Application Route : inhalation (vapour)
Exposure time : 18 month(s)
Result : negative

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 451
Result : negative

Reproductive toxicity

May damage the unborn child.

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Components:**Propylene glycol:**

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

Effects on foetal develop- : Test Type: Embryo-foetal development
ment Species: Mouse
Application Route: Ingestion
Result: negative

N,N-Dimethylacetamide:

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

Effects on foetal develop- : Test Type: Embryo-foetal development
ment Species: Rat
Application Route: Inhalation
Result: positive

Reproductive toxicity - As- : Clear evidence of adverse effects on development, based on
sessment animal experiments.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal develop- : Test Type: Embryo-foetal development
ment Species: Mouse
Application Route: Ingestion
Result: negative

Trichlormethiazide:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Early Embryonic Development: NOAEL: 1,000 mg/kg body weight
Result: No effects on fertility and early embryonic develop-
ment were detected.
Remarks: Based on data from similar materials

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Test Type: Fertility/early embryonic development
Species: Mouse
Application Route: Oral
Early Embryonic Development: NOAEL: 3,000 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.
Remarks: Based on data from similar materials

dexamethasone:

Effects on foetal development

: Test Type: Development
Species: Mouse
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 6 mg/kg body weight
Result: Specific developmental abnormalities, Cleft palate

Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: NOAEL: 0.025 mg/kg body weight
Result: Specific developmental abnormalities

Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: ≥ 0.062 mg/kg body weight
Result: Specific developmental abnormalities

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: ≥ 0.02 mg/kg body weight
Result: Skeletal and visceral variations, Fetal growth retardation

Reproductive toxicity - Assessment : May damage the unborn child.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:**dexamethasone:**

Exposure routes : Oral
Target Organs : Adrenal gland, Immune system, thymus gland
Assessment : May cause damage to organs through prolonged or repeated exposure.

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Repeated dose toxicity**Components:****Propylene glycol:**

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

N,N-Dimethylacetamide:

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|-------------------|-----------------------|
| Species | : Rat |
| NOAEL | : 90 mg/m3 |
| LOAEL | : 360 mg/m3 |
| Application Route | : inhalation (vapour) |
| Exposure time | : 24 Months |

Benzyl alcohol:

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|-------------------|-------------------------------|
| Species | : Rat |
| NOAEL | : 1.072 mg/l |
| Application Route | : inhalation (dust/mist/fume) |
| Exposure time | : 28 Days |
| Method | : OECD Test Guideline 412 |

dexamethasone:

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| Species | : Rat |
| NOAEL | : 0.0015 mg/kg |
| Application Route | : Oral |
| Exposure time | : 7 d |
| Target Organs | : Liver |
| Remarks | : Significant toxicity observed in testing |

| | |
|-------------------|--|
| Species | : Rat |
| LOAEL | : 0.003 mg/kg |
| Application Route | : Oral |
| Exposure time | : 90 d |
| Target Organs | : Blood, Adrenal gland, thymus gland |
| Remarks | : Significant toxicity observed in testing |

| | |
|-------------------|--|
| Species | : Dog |
| LOAEL | : 0.125 mg/kg |
| Application Route | : Oral |
| Exposure time | : 6 Weeks |
| Target Organs | : Adrenal gland |
| Remarks | : Significant toxicity observed in testing |

| | |
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| Species | : Rat |
| LOAEL | : 0.4 mg/kg |
| Application Route | : Oral |

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Exposure time : 3 Months
 Target Organs : Immune system
 Remarks : Significant toxicity observed in testing

Species : Dog
 LOAEL : 8 mg/kg
 Application Route : Oral
 Exposure time : 3 Months
 Target Organs : Immune system
 Remarks : Significant toxicity observed in testing

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Trichlormethiazide:

General Information : Symptoms: Dizziness, Drowsiness, effects on blood pressure, Fatigue, Headache, hyperkalemia, hypertension, hypotension
 Remarks: The most common side effects are:

dexamethasone:

Ingestion : Target Organs: Immune system
 Target Organs: Adrenal gland
 Target Organs: Bone
 Symptoms: muscle weakness

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
 Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
 Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l
 Exposure time: 18 h

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N,N-Dimethylacetamide:

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|---|---|--|
| Toxicity to fish | : | LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 500 mg/l Exposure time: 48 h Method: Directive 67/548/EEC, Annex V, C.2. |
| Toxicity to algae/aquatic plants | : | EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l Exposure time: 72 h EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l Exposure time: 72 h |
| Toxicity to microorganisms | : | EC10: > 1,995 mg/l Exposure time: 30 min |

Benzyl alcohol:

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|--|---|--|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 |

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- | | | |
|---|---|--|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 56 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |

**Dexamethasone / Trichlormethiazide Formula-
tion**

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NOEC (Pseudokirchneriella subcapitata (green algae)): 9.2 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.033 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition

Method: OECD Test Guideline 209

Persistence and degradability**Components:****Propylene glycol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

N,N-Dimethylacetamide:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 70 %
Exposure time: 28 d
Method: OECD Test Guideline 301C
Remarks: The test was conducted equivalent or similar to guideline

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

dexamethasone:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 3.54 d
Method: OECD Test Guideline 314

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Bioaccumulative potential**Components:****Propylene glycol:**

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

Benzyl alcohol:

| | | |
|--|---|---------------|
| Partition coefficient: n-octanol/water | : | log Pow: 1.05 |
|--|---|---------------|

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| | | |
|--|---|---------------|
| Partition coefficient: n-octanol/water | : | log Pow: 1.83 |
|--|---|---------------|

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

| | | |
|------------------------|---|---|
| Waste from residues | : | Do not dispose of waste into sewer. Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

| | | |
|---------------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Environmentally hazardous | : | no |

IATA-DGR

| | | |
|----------------------|---|----------------|
| UN/ID No. | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |

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Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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 : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Therapeutic Goods (Poisons Standard) Instrument : Schedule 5 (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

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IECSC : not determined

SECTION 16: ANY OTHER RELEVANT INFORMATION**Further information**

Revision Date : 20.06.2025
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/>

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
AU OEL / TWA : Exposure standard - time weighted average

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

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recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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