SAFETY DATA SHEET

Dexamethasone / Trichlormethiazide Formulation

SECTION 1. IDENTIFICATION

Product name : Dexamethasone / Trichlormethiazide Formulation
Other means of identification : No data available

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 in accordance with the Hazardous Products Regulations
Eye irritation : Category 2A
Reproductive toxicity : Category 1B

GHS label elements
Hazard pictograms : ⬇️ ⬆️

Signal Word : Danger
Hazard Statements : 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.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves, protective clothing, eye protection and 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 attention.
P337 + P313 If eye irritation persists: Get medical attention.

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Propylene glycol</td>
<td>1,2-Propanediol</td>
<td>57-55-6</td>
<td>80.75</td>
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<tr>
<td></td>
<td>N,N-Dimethylacetamide</td>
<td>Acetamide, N,N-dimethyl-</td>
<td>127-19-5</td>
<td>16.02</td>
</tr>
<tr>
<td></td>
<td>Benzyl alcohol</td>
<td>Benzenemethanol</td>
<td>100-51-6</td>
<td>2.24</td>
</tr>
<tr>
<td></td>
<td>Trichlormethiazide</td>
<td>No data available</td>
<td>133-67-5</td>
<td>0.86</td>
</tr>
<tr>
<td></td>
<td>Dexamethasone</td>
<td>No data available</td>
<td>50-02-2</td>
<td>0.05</td>
</tr>
</tbody>
</table>

### 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.
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:**
Causes serious eye irritation.
and effects, both acute and delayed
Protection of first-aiders
Notes to physician

May damage the unborn child.
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).
Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting:
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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.

Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.
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Dexamethasone / Trichlormethiazide Formulation

Version 1.8 Revision Date: 04/04/2023 SDS Number: 5408267-00009 Date of last issue: 10/01/2022 Date of first issue: 02/13/2020

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. Do not breathe vapors or spray mist. 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. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled 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 Self-reactive substances and mixtures Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (Vapour and aerosols)</td>
<td>50 ppm 155 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>TWA</td>
<td>10 ppm 36 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA EV</td>
<td>10 ppm 36 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Trichlormethiazide</td>
<td>133-67-5</td>
<td>TWA</td>
<td>1 μg/m³ (OEB4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 μg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>TWA</td>
<td>10 μg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Further information: Skin

| Wipe limit | 100 µg/100 cm² | Internal |

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>N-Methylacetamide</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>30 mg/g Creatinine</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

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 vapor 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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>colorless</td>
</tr>
<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
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<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
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</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
</tbody>
</table>


**EXPLOSIVE PROPERTIES**
- Not explosive

**OXIDIZING PROPERTIES**
- The substance or mixture is not classified as oxidizing.

**MOLECULAR WEIGHT**
- No data available

**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

#### Information on likely routes of exposure

- **Inhalation**
- **Skin contact**
- **Ingestion**
- **Eye contact**

**Acute toxicity**
- Not classified based on available information.

**Product:**

- **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:

**Acute oral toxicity:**  
**LD50 (Rat):** 4,800 mg/kg

**Acute inhalation toxicity:**  
**LC50 (Rat):** 2.2 mg/l  
**Exposure time:** 4 h  
**Test atmosphere:** dust/mist

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

### Benzyl alcohol:

**Acute oral toxicity:**  
**LD50 (Rat):** 1,620 mg/kg

**Acute inhalation toxicity:**  
**LC50 (Rat):** > 4.178 mg/l  
**Exposure time:** 4 h  
**Test atmosphere:** dust/mist  
**Method:** OECD Test Guideline 403

### 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
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
Method: OECD Test Guideline 405

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 sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Propylene glycol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
N,N-Dimethylacetamide:
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Benzyl alcohol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

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:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
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:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative
## Dexamethasone / Trichlormethiazide Formulation

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

- **Test Type:** in vitro test
  - **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 (vapor)
- **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.

### Components:

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

- **Effects on fetal development**
  - **Test Type:** Embryo-fetal development
  - **Species:** Mouse
  - **Application Route:** Ingestion
**N,N-Dimethylacetamide:**

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

**Effects on fetal development**
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Inhalation
- Result: positive

**Reproductive toxicity - Assessment**
- Clear evidence of adverse effects on development, based on 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 fetal development**
- Test Type: Embryo-fetal development
- 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 development were detected.
- Remarks: Based on data from similar materials

- 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 fetal 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., Retardations.
Species: Rat
Application Route: Subcutaneous

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:
Routes of exposure: Oral
Target Organs: Adrenal gland, Immune system, thymus gland
Assessment: May cause 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 y

N,N-Dimethylacetamide:
Species: Rat
NOAEL: 90 mg/m³
LOAEL: 360 mg/m³
Application Route: inhalation (vapor)
Exposure time: 24 Months
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Benzyl alcohol:
Species: Rat
NOAEL: 1.072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

Dexamethasone:
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: Rat
LOAEL: 0.125 mg/kg
Application Route: Oral
Exposure time: 6 Weeks
Target Organs: Adrenal gland
Remarks: Significant toxicity observed in testing

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

#### N,N-Dimethylacetamide:
- **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:
- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): 460 mg/l, Exposure time: 96 h
### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Component</th>
<th>EC50 (Daphnia magna (Water flea)):</th>
<th>Exposure time:</th>
<th>Method: OECD Test Guideline 202</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>230 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>&gt; 56 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Component</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>Exposure time:</th>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>770 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>&gt; 9.2 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

### NOEC (Pseudokirchneriella subcapitata (green algae))

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)):</th>
<th>Exposure time:</th>
<th>Method: OECD Test Guideline 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>310 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>9.2 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Daphnia magna (Water flea)):</th>
<th>Exposure time:</th>
<th>Method: OECD Test Guideline 211</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>51 mg/l</td>
<td>21 d</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Pimephales promelas (fathead minnow)):</th>
<th>Exposure time:</th>
<th>Method: OECD Test Guideline 210</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>0.033 mg/l</td>
<td>32 d</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Component</th>
<th>EC50:</th>
<th>Exposure time:</th>
<th>Test Type:</th>
<th>Method: OECD Test Guideline 209</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>&gt; 1,000 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### NOEC

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC:</th>
<th>Exposure time:</th>
<th>Test Type:</th>
<th>Method: OECD Test Guideline 209</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>1,000 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Persistence and degradability

**Components:**

**Propylene glycol:**

Biodegradability: Result: Readily biodegradable.
**Biodegradation:**

- **N,N-Dimethylacetamide:**
  - Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 70 %
  - Exposure time: 28 d
  - Remarks: The 10 day time window criterion is not fulfilled.

- **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

**Bioaccumulative potential**

**Components:**

- **Propylene glycol:**
  - Partition coefficient: n-octanol/water: log Pow: -1.07

- **Benzyl alcohol:**
  - Partition coefficient: n-octanol/water: log Pow: 1.05

- **Dexamethasone:**
  - Partition coefficient: n-octanol/water: log Pow: 1.83

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)


CA BC OEL : Canada. British Columbia OEL

CA ON OEL : Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.

CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants

ACGIH / TWA : 8-hour, time-weighted average

CA AB OEL / TWA : 8-hour Occupational exposure limit

CA BC OEL / TWA : 8-hour time weighted average

CA ON OEL / TWA : Time-Weighted Average Limit (TWA)
SAFETY DATA SHEET

Dexamethasone / Trichlormethiazide Formulation

Version 1.8  
Revision Date: 04/04/2023  
SDS Number: 5408267-00009  
Date of last issue: 10/01/2022

CA QC OEL / TWAEV : Time-weighted average exposure value

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.os. - 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


Revision Date : 04/04/2023
Date format : mm/dd/yyyy

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.

CA / ZB