SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Dexamethasone / Trichlormethiazide Formulation

SECTION 1. IDENTIFICATION

Product name : Dexamethasone / Trichlormethiazide Formulation

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 OSHA Hazard Communication Standard (29 CFR 1910.1200)
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.

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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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>80.75</td>
</tr>
<tr>
<td>N,N-Dimethylethacetamide</td>
<td>127-19-5</td>
<td>16.02</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>2.24</td>
</tr>
<tr>
<td>Trichlormethiazide</td>
<td>133-67-5</td>
<td>0.86</td>
</tr>
<tr>
<td>Dexamethasone</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 and effects, both acute and delayed : 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. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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 (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 spills 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.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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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</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm, 35 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>TWA</td>
<td>10 ppm, 35 mg/m³</td>
<td>OSHA Z-1</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
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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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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>Value</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>
<td>No data available</td>
</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>
</tr>
<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>
</tbody>
</table>
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 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: > 5,000 mg/kg
  Method: Calculation method
Acute inhalation toxicity : Acute toxicity estimate: 12.8 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method
Acute dermal toxicity : Acute toxicity estimate: > 5,000 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

**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:**
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
IARC  Group 2B: Possibly carcinogenic to humans  
N,N-Dimethylacetamide  127-19-5

OSHA  No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP  No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**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

**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
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<tbody>
<tr>
<td>2.7</td>
<td>09/30/2023</td>
<td>5408279-00009</td>
<td>04/04/2023</td>
<td>02/13/2020</td>
</tr>
</tbody>
</table>

**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.

**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.
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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: Inhilation (vapor)
Exposure time: 24 Months

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
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</tbody>
</table>

- **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 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: 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

**Dexamethasone:**

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
- 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: 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
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tion

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

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

49 CFR
Not regulated as a dangerous good
SAFETY DATA SHEET
down to the OSHA Hazard Communication Standard

Dexamethasone / Trichlormethiazide Formulation

Version 2.7  Revision Date: 09/30/2023  SDS Number: 5408279-00009  Date of last issue: 04/04/2023  Date of first issue: 02/13/2020

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards :
Reproductive toxicity
Serious eye damage or eye irritation

SARA 313 :
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
Propylene glycol 57-55-6
N,N-Dimethylacetamide 127-19-5
Benzyl alcohol 100-51-6

California Prop. 65
WARNING: This product can expose you to chemicals including N,N-Dimethylacetamide, which is/are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
N,N-Dimethylacetamide 127-19-5

California Permissible Exposure Limits for Chemical Contaminants
N,N-Dimethylacetamide 127-19-5

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Dexamethasone / Trichlormethiazide Formula-
tion

Version 2.7 Revision Date: 09/30/2023 SDS Number: 5408279-00009

Date of last issue: 04/04/2023 Date of first issue: 02/13/2020

NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
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<td>2</td>
<td>0</td>
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</tbody>
</table>

Special hazard

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA: 8-hour, time-weighted average
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA: 8-hour time weighted average
US WEEL / TWA: 8-hr TWA

AICL - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECX - Concentration associated with x% response; EHS - Extremely Hazardous Substance; E| - 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse)
Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09/30/2023

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.

US / Z8