

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

### 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

Version 1.9      Revision Date: 09/30/2023      SDS Number: 5408267-00010      Date of last issue: 04/04/2023  
Date of first issue: 02/13/2020

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

### Components

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

## 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|                |                              |                              |                                                                   |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|
| Version<br>1.9 | Revision Date:<br>09/30/2023 | SDS Number:<br>5408267-00010 | Date of last issue: 04/04/2023<br>Date of first issue: 02/13/2020 |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|

|                                                             |   |                                                                                                                                                                             |
|-------------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye irritation.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical                                                                                                                                                      |
| Unsuitable extinguishing media                 | : | None known.                                                                                                                                                                                                                                     |
| Specific hazards during fire fighting          | : | Exposure to combustion products may be a hazard to health.                                                                                                                                                                                      |
| Hazardous combustion products                  | : | Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )                                                                                                                                                                                             |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.                                                                                                                                            |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

|                                                                     |   |                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).                                                                                                                                                                                                                                                                            |
| Environmental precautions                                           | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.                                                                                                                 |
| Methods and materials for containment and cleaning up               | : | Soak up with inert absorbent material.<br>For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absorbent.<br>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

Version 1.9      Revision Date: 09/30/2023      SDS Number: 5408267-00010      Date of last issue: 04/04/2023  
Date of first issue: 02/13/2020

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.

### 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

| Components            | CAS-No.  | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis     |
|-----------------------|----------|-------------------------------|------------------------------------------------|-----------|
| Propylene glycol      | 57-55-6  | TWA (Vapour and aerosols)     | 50 ppm<br>155 mg/m <sup>3</sup>                | CA ON OEL |
|                       |          | TWA (aerosol)                 | 10 mg/m <sup>3</sup>                           | CA ON OEL |
| N,N-Dimethylacetamide | 127-19-5 | TWA                           | 10 ppm<br>36 mg/m <sup>3</sup>                 | CA AB OEL |
|                       |          | TWA                           | 10 ppm                                         | CA BC OEL |
|                       |          | TWAEV                         | 10 ppm<br>36 mg/m <sup>3</sup>                 | CA QC OEL |
|                       |          | TWA                           | 10 ppm                                         | ACGIH     |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

Version 1.9      Revision Date: 09/30/2023      SDS Number: 5408267-00010      Date of last issue: 04/04/2023  
Date of first issue: 02/13/2020

|                    |                           |            |                            |          |
|--------------------|---------------------------|------------|----------------------------|----------|
| Trichlormethiazide | 133-67-5                  | TWA        | 1 µg/m3 (OEB4)             | Internal |
|                    |                           | Wipe limit | 10 µg/100 cm <sup>2</sup>  | Internal |
| Dexamethasone      | 50-02-2                   | TWA        | 10 µg/m3 (OEB 3)           | Internal |
|                    | Further information: Skin |            |                            |          |
|                    |                           | Wipe limit | 100 µg/100 cm <sup>2</sup> | Internal |

### Biological occupational exposure limits

| Components            | CAS-No.  | Control parameters | Biological specimen | Sam-pling time                   | Permissible concentra-tion | Basis     |
|-----------------------|----------|--------------------|---------------------|----------------------------------|----------------------------|-----------|
| N,N-Dimethylacetamide | 127-19-5 | N-Methylaceta-mide | Urine               | End of shift at end of work-week | 30 mg/g creatinine         | ACGIH BEI |

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

### Personal protective equipment

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

Filter type : Combined particulates and organic 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|                |                              |                              |                                                                   |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|
| Version<br>1.9 | Revision Date:<br>09/30/2023 | SDS Number:<br>5408267-00010 | Date of last issue: 04/04/2023<br>Date of first issue: 02/13/2020 |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|

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

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

|                           |   |                                                          |
|---------------------------|---|----------------------------------------------------------|
| 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: > 2,000 mg/kg<br>Method: Calculation method                                                |
| Acute inhalation toxicity | : | Acute toxicity estimate: > 5 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: Calculation method |
| Acute dermal toxicity     | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method                                                |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

### Components:

#### **Propylene glycol:**

|                           |   |                                                                                                   |
|---------------------------|---|---------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 22,000 mg/kg                                                                          |
| Acute inhalation toxicity | : | LC50 (Rat): > 44.9 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist                       |
| Acute dermal toxicity     | : | LD50 (Rabbit): > 2,000 mg/kg<br>Assessment: The substance or mixture has no acute dermal toxicity |

#### **N,N-Dimethylacetamide:**

|                           |   |                                                                                                                       |
|---------------------------|---|-----------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 4,800 mg/kg                                                                                               |
| Acute inhalation toxicity | : | LC50 (Rat): 2.2 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist                                              |
| Acute dermal toxicity     | : | Acute toxicity estimate: 1,100 mg/kg<br>Method: Expert judgment<br>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<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 403 |

#### **Trichlormethiazide:**

|                     |   |                                                                                       |
|---------------------|---|---------------------------------------------------------------------------------------|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg<br>Symptoms: hyperglycemia<br><br>LD50 (Mouse): 2,600 mg/kg |
|---------------------|---|---------------------------------------------------------------------------------------|

#### **Dexamethasone:**

|                                                 |   |                                                              |
|-------------------------------------------------|---|--------------------------------------------------------------|
| Acute oral toxicity                             | : | LD50 (Rat): > 2,000 mg/kg<br><br>LD50 (Mouse): > 6,500 mg/kg |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 14 mg/kg<br>Application Route: Subcutaneous      |

#### **Skin corrosion/irritation**

Not classified based on available information.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula- tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

### 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

### 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)<br>Result: negative |
|-----------------------|--------------------------------------------------------------------------|

|  |                                                                                                       |
|--|-------------------------------------------------------------------------------------------------------|
|  | Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: negative |
|--|-------------------------------------------------------------------------------------------------------|

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

##### N,N-Dimethylacetamide:

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

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula- tion

|                |                              |                              |                                                                   |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|
| Version<br>1.9 | Revision Date:<br>09/30/2023 | SDS Number:<br>5408267-00010 | Date of last issue: 04/04/2023<br>Date of first issue: 02/13/2020 |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

### 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  
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

#### 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

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:  $\geq 0.062$  mg/kg body weight  
Result: Specific developmental abnormalities.

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL:  $\geq 0.02$  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.

### 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

### Repeated dose toxicity

#### Components:

##### **Propylene glycol:**

|                   |                      |
|-------------------|----------------------|
| Species           | : Rat, male          |
| NOAEL             | : $\geq 1,700$ mg/kg |
| Application Route | : Ingestion          |
| Exposure time     | : 2 y                |

##### **N,N-Dimethylacetamide:**

|                   |                         |
|-------------------|-------------------------|
| Species           | : Rat                   |
| NOAEL             | : 90 mg/m <sup>3</sup>  |
| LOAEL             | : 360 mg/m <sup>3</sup> |
| Application Route | : inhalation (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                                     |
| 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  |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula- tion

|                |                              |                              |                                                                   |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|
| Version<br>1.9 | Revision Date:<br>09/30/2023 | SDS Number:<br>5408267-00010 | Date of last issue: 04/04/2023<br>Date of first issue: 02/13/2020 |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|

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

### Benzyl alcohol:

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

### Dexamethasone:

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

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  
Method: OECD Test Guideline 314

### Bioaccumulative potential

#### Components:

##### **Propylene glycol:**

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula- tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

### 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 : 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

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

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula-tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

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 AB OEL       | : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)                                                                      |
| 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 air-borne 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)                                                                                                        |
| CA QC OEL / TWA | : 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.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; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Dexamethasone / Trichlormethiazide Formula- tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 1.9     | 09/30/2023     | 5408267-00010 | Date of first issue: 02/13/2020 |

---

stances 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/30/2023  
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 / Z8