

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name : Dexamethasone / Trichlormethiazide Formulation

**1.2 Relevant identified uses of the substance or mixture and uses advised against**Use of the Sub-  
stance/Mixture : Veterinary productRecommended restrictions  
on use : Not applicable**1.3 Details of the supplier of the safety data sheet**Company : MSD  
20 Spartan Road  
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com**1.4 Emergency telephone number**

+1-908-423-6000

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

|                                    |                                            |
|------------------------------------|--------------------------------------------|
| Eye irritation, Category 2         | H319: Causes serious eye irritation.       |
| Skin sensitisation, Category 1     | H317: May cause an allergic skin reaction. |
| Reproductive toxicity, Category 1B | H360D: May damage the unborn child.        |

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Danger

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

# Dexamethasone / Trichlormethiazide Formula- tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

Precautionary statements :

**Prevention:**

P201 Obtain special instructions before use.  
 P264 Wash skin thoroughly after handling.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
 P337 + P313 If eye irritation persists: Get medical advice/ attention.

Hazardous components which must be listed on the label:

N,N-Dimethylacetamide  
 Benzyl alcohol

**Additional Labelling**

Restricted to professional users.

**2.3 Other hazards**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

**3.2 Mixtures****Components**

| Chemical name         | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                                                    | Concentration<br>(% w/w) |
|-----------------------|-------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------|
| N,N-Dimethylacetamide | 127-19-5<br>204-826-4<br>616-011-00-4                 | Acute Tox. 4; H332<br>Acute Tox. 4; H312<br>Eye Irrit. 2; H319<br>Repr. 1B; H360D | >= 10 - < 20             |
| Benzyl alcohol        | 100-51-6<br>202-859-9<br>603-057-00-5                 | Acute Tox. 4; H302<br>Eye Irrit. 2; H319<br>Skin Sens. 1B;<br>H317                | >= 1 - < 10              |
| Trichlormethiazide    | 133-67-5<br>205-118-8                                 |                                                                                   | >= 1 - < 10              |
| dexamethasone         | 50-02-2<br>200-003-9                                  | Repr. 1B; H360D<br>STOT RE 2; H373<br>(Adrenal gland,                             | >= 0,025 - < 0,1         |

## Dexamethasone / Trichlormethiazide Formula- tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

|  |  |                                                               |  |
|--|--|---------------------------------------------------------------|--|
|  |  | Immune system,<br>thymus gland)<br>Aquatic Chronic 1;<br>H410 |  |
|  |  | M-Factor (Chronic<br>aquatic toxicity): 1                     |  |

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- |                            |   |                                                                                                                                                                                                                       |
|----------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice             | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.                                                                |
| 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).                                           |
| If inhaled                 | : | If inhaled, remove to fresh air.<br>Get medical attention.                                                                                                                                                            |
| In case of skin contact    | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.                                                    |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.                                                                                                                 |

#### 4.2 Most important symptoms and effects, both acute and delayed

- |       |   |                                                                                                        |
|-------|---|--------------------------------------------------------------------------------------------------------|
| Risks | : | May cause an allergic skin reaction.<br>Causes serious eye irritation.<br>May damage the unborn child. |
|-------|---|--------------------------------------------------------------------------------------------------------|

#### 4.3 Indication of any immediate medical attention and special treatment needed

- |           |   |                                         |
|-----------|---|-----------------------------------------|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|-----------------------------------------|

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
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| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

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

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)

**5.3 Advice for firefighters**

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

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.

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

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

**6.2 Environmental precautions**

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can

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tion**

|         |                |               |                                 |
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| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

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.

**6.4 Reference to other sections**

See sections: 7, 8, 11, 12 and 13.

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**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

- |                         |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical measures      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Avoid breathing mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Take care to prevent spills, waste and minimize release to the environment.                                                                                                                                                                   |
| Hygiene measures        | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

**7.2 Conditions for safe storage, including any incompatibilities**

- |                                               |   |                                                                                                                                                       |
|-----------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.             |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives |

# Dexamethasone / Trichlormethiazide Formula- tion

Version 8.1      Revision Date: 20.06.2025      SDS Number: 5408280-00016      Date of last issue: 14.04.2025  
Date of first issue: 13.02.2020

## Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

| Components                                                                                                                          | CAS-No.  | Value type (Form of exposure) | Control parameters             | Basis      |
|-------------------------------------------------------------------------------------------------------------------------------------|----------|-------------------------------|--------------------------------|------------|
| N,N-Dimethylacetamide                                                                                                               | 127-19-5 | OEL-RL                        | 20 ppm                         | ZA OEL     |
| Further information: danger of cutaneous absorption, Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents |          |                               |                                |            |
|                                                                                                                                     |          | TWA                           | 10 ppm<br>36 mg/m <sup>3</sup> | 2000/39/EC |
|                                                                                                                                     |          | STEL                          | 20 ppm<br>72 mg/m <sup>3</sup> | 2000/39/EC |
|                                                                                                                                     |          | TWA                           | 10 ppm<br>36 mg/m <sup>3</sup> | 2004/37/EC |
|                                                                                                                                     |          | STEL                          | 20 ppm<br>72 mg/m <sup>3</sup> | 2004/37/EC |
| Trichlormethiazide                                                                                                                  | 133-67-5 | TWA                           | 1 µg/m <sup>3</sup> (OEB4)     | Internal   |
|                                                                                                                                     |          | Wipe limit                    | 10 µg/100 cm <sup>2</sup>      | Internal   |
| dexamethasone                                                                                                                       | 50-02-2  | TWA                           | 10 µg/m <sup>3</sup> (OEB 3)   | Internal   |
| Further information: Skin                                                                                                           |          |                               |                                |            |
|                                                                                                                                     |          | Wipe limit                    | 100 µg/100 cm <sup>2</sup>     | Internal   |

#### Biological occupational exposure limits

| Substance name        | CAS-No.  | Control parameters                               | Sampling time                   | Basis  |
|-----------------------|----------|--------------------------------------------------|---------------------------------|--------|
| N,N-Dimethylacetamide | 127-19-5 | N-Methylacetamide:<br>30 mg/g creatinine (Urine) | End of shift at end of workweek | ZA BEI |

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name | End Use   | Exposure routes | Potential health effects   | Value                 |
|----------------|-----------|-----------------|----------------------------|-----------------------|
| Benzyl alcohol | Workers   | Inhalation      | Long-term systemic effects | 22 mg/m <sup>3</sup>  |
|                | Workers   | Inhalation      | Acute systemic effects     | 110 mg/m <sup>3</sup> |
|                | Workers   | Skin contact    | Long-term systemic effects | 8 mg/kg bw/day        |
|                | Workers   | Skin contact    | Acute systemic effects     | 40 mg/kg bw/day       |
|                | Consumers | Inhalation      | Long-term systemic effects | 5,4 mg/m <sup>3</sup> |

## Dexamethasone / Trichlormethiazide Formula- tion

Version 8.1      Revision Date: 20.06.2025      SDS Number: 5408280-00016      Date of last issue: 14.04.2025  
Date of first issue: 13.02.2020

|                           |           |              |                               |                      |
|---------------------------|-----------|--------------|-------------------------------|----------------------|
|                           | Consumers | Inhalation   | Acute systemic ef-<br>fects   | 27 mg/m3             |
|                           | Consumers | Skin contact | Long-term systemic<br>effects | 4 mg/kg<br>bw/day    |
|                           | Consumers | Skin contact | Acute systemic ef-<br>fects   | 20 mg/kg<br>bw/day   |
|                           | Consumers | Ingestion    | Long-term systemic<br>effects | 4 mg/kg<br>bw/day    |
|                           | Consumers | Ingestion    | Acute systemic ef-<br>fects   | 20 mg/kg<br>bw/day   |
| N,N-<br>Dimethylacetamide | Workers   | Inhalation   | Long-term systemic<br>effects | 36 mg/m3             |
|                           | Workers   | Inhalation   | Acute systemic ef-<br>fects   | 36 mg/m3             |
|                           | Workers   | Skin contact | Acute systemic ef-<br>fects   | 13,6 mg/kg<br>bw/day |
|                           | Consumers | Inhalation   | Long-term local ef-<br>fects  | 7 mg/m3              |
|                           | Consumers | Skin contact | Long-term systemic<br>effects | 2,7 mg/kg<br>bw/day  |
|                           | Consumers | Ingestion    | Long-term systemic<br>effects | 1 mg/kg<br>bw/day    |
| Propylene glycol          | Workers   | Inhalation   | Long-term local ef-<br>fects  | 10 mg/m3             |
|                           | Workers   | Inhalation   | Long-term systemic<br>effects | 168 mg/m3            |
|                           | Consumers | Inhalation   | Long-term local ef-<br>fects  | 10 mg/m3             |
|                           | Consumers | Inhalation   | Long-term systemic<br>effects | 50 mg/m3             |

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

| Substance name        | Environmental Compartment | Value                          |
|-----------------------|---------------------------|--------------------------------|
| Benzyl alcohol        | Fresh water               | 1 mg/l                         |
|                       | Marine water              | 0,1 mg/l                       |
|                       | Intermittent use/release  | 2,3 mg/l                       |
|                       | Sewage treatment plant    | 39 mg/l                        |
|                       | Fresh water sediment      | 5,27 mg/kg                     |
|                       | Marine sediment           | 0,527 mg/kg                    |
| N,N-Dimethylacetamide | Soil                      | 0,456 mg/kg                    |
|                       | Fresh water               | 0,5 mg/l                       |
|                       | Marine water              | 0,0966 mg/l                    |
|                       | Intermittent use/release  | 5 mg/l                         |
|                       | Sewage treatment plant    | 485 mg/l                       |
|                       | Fresh water sediment      | 2,27 mg/kg                     |
| Propylene glycol      | Soil                      | 0,15 mg/kg                     |
|                       | Fresh water               | 260 mg/l                       |
|                       | Freshwater - intermittent | 183 mg/l                       |
|                       | Marine water              | 26 mg/l                        |
|                       | Sewage treatment plant    | 20000 mg/l                     |
|                       | Fresh water sediment      | 572 mg/kg dry<br>weight (d.w.) |

## Dexamethasone / Trichlormethiazide Formula- tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

|  |                 |                              |
|--|-----------------|------------------------------|
|  | Marine sediment | 57,2 mg/kg dry weight (d.w.) |
|  | Soil            | 50 mg/kg dry weight (d.w.)   |

### 8.2 Exposure controls

#### Engineering measures

The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

#### Personal protective equipment

- |                          |   |                                                                                                                                                                                                                                                                                                                |
|--------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Eye/face protection      | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Hand protection          | : |                                                                                                                                                                                                                                                                                                                |
| Material                 | : | Chemical-resistant gloves                                                                                                                                                                                                                                                                                      |
| Remarks                  | : | Consider double gloving.                                                                                                                                                                                                                                                                                       |
| Skin and body protection | : | Work uniform or laboratory coat.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing.                    |
| Respiratory protection   | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.                                                                                                                                           |
| Filter type              | : | Combined particulates and organic vapour type (A-P)                                                                                                                                                                                                                                                            |

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

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



**Dexamethasone / Trichlormethiazide Formula-  
tion**

|                |                              |                              |                                                                   |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|
| Version<br>8.1 | Revision Date:<br>20.06.2025 | SDS Number:<br>5408280-00016 | Date of last issue: 14.04.2025<br>Date of first issue: 13.02.2020 |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|

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|                                                  |   |                                                          |
|--------------------------------------------------|---|----------------------------------------------------------|
| pH                                               | : | No data available                                        |
| Melting point/freezing point                     | : | No data available                                        |
| Initial boiling point and boiling range          | : | No data available                                        |
| Flash point                                      | : | No data available                                        |
| Evaporation rate                                 | : | No data available                                        |
| Flammability (solid, gas)                        | : | Not applicable                                           |
| Flammability (liquids)                           | : | No data available                                        |
| Upper explosion limit / Upper flammability limit | : | No data available                                        |
| Lower explosion limit / Lower flammability limit | : | No data available                                        |
| Vapour pressure                                  | : | No data available                                        |
| Relative vapour density                          | : | No data available                                        |
| Relative density                                 | : | No data available                                        |
| Density                                          | : | No data available                                        |
| Solubility(ies)                                  |   |                                                          |
| Water solubility                                 | : | No data available                                        |
| Partition coefficient: n-octanol/water           | : | Not applicable                                           |
| Auto-ignition temperature                        | : | No data available                                        |
| Decomposition temperature                        | : | No data available                                        |
| Viscosity                                        |   |                                                          |
| Viscosity, kinematic                             | : | No data available                                        |
| Explosive properties                             | : | Not explosive                                            |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing. |

**9.2 Other information**

|                  |   |                   |
|------------------|---|-------------------|
| Molecular weight | : | No data available |
| Particle size    | : | Not applicable    |

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

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**SECTION 10: Stability and reactivity****10.1 Reactivity**

Not classified as a reactivity hazard.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Hazardous reactions : Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

Conditions to avoid : None known.

**10.5 Incompatible materials**

Materials to avoid : Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

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**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg  
Method: Calculation method

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

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg  
Method: Calculation method

**Components:****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

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

Test atmosphere: dust/mist

Acute dermal toxicity : Acute toxicity estimate: 1.100 mg/kg  
Method: Expert judgement  
Remarks: Based on national or regional regulation.

**Benzyl alcohol:**

Acute oral toxicity : LD50 (Rat): 1.200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,4 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity

**Trichlormethiazide:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
Symptoms: hyperglycemia

LD50 (Mouse): 2.600 mg/kg

**dexamethasone:**

Acute oral toxicity : LD50 (Rat): &gt; 2.000 mg/kg

LD50 (Mouse): &gt; 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:****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

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

---

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****N,N-Dimethylacetamide:**

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

**Benzyl alcohol:**

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

**dexamethasone:**

|         |                       |
|---------|-----------------------|
| Species | : Rabbit              |
| Result  | : Mild eye irritation |

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****N,N-Dimethylacetamide:**

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

**Benzyl alcohol:**

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

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****N,N-Dimethylacetamide:**

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

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

---

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 assay  
Test system: mouse lymphoma cells  
Result: negative

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

**Carcinogenicity**

Not classified based on available information.

**Components:****N,N-Dimethylacetamide:**

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

**Benzyl alcohol:**

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

**Reproductive toxicity**

May damage the unborn child.

## Dexamethasone / Trichlormethiazide Formula- tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

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### Components:

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

|                                    |   |                                                                                                                            |
|------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility               | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Inhalation<br>Result: negative |
| Effects on foetal development      | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Inhalation<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative                                                            |

#### **Trichlormethiazide:**

|                      |   |                                                                                                                                                                                                                                                                                                 |
|----------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Oral<br>Early Embryonic Development: NOAEL: 1.000 mg/kg body weight<br>Result: No effects on fertility and early embryonic development were detected.<br>Remarks: Based on data from similar materials   |
|                      |   | Test Type: Fertility/early embryonic development<br>Species: Mouse<br>Application Route: Oral<br>Early Embryonic Development: NOAEL: 3.000 mg/kg body weight<br>Result: No effects on fertility and early embryonic development were detected.<br>Remarks: Based on data from similar materials |

#### **dexamethasone:**

|                               |   |                                                                             |
|-------------------------------|---|-----------------------------------------------------------------------------|
| Effects on foetal development | : | Test Type: Development<br>Species: Mouse<br>Application Route: Subcutaneous |
|-------------------------------|---|-----------------------------------------------------------------------------|

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

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, Fetal growth retardation

Reproductive toxicity - Assessment : May damage the unborn child.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Components:****dexamethasone:**

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

**Repeated dose toxicity****Components:****N,N-Dimethylacetamide:**

Species : Rat  
NOAEL : 90 mg/m<sup>3</sup>  
LOAEL : 360 mg/m<sup>3</sup>  
Application Route : inhalation (vapour)  
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 / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

**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 : Dog  
LOAEL : 0,125 mg/kg  
Application Route : Oral  
Exposure time : 6 Weeks  
Target Organs : Adrenal gland  
Remarks : Significant toxicity observed in testing

Species : Rat  
LOAEL : 0,4 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Immune system  
Remarks : Significant toxicity observed in testing

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

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Trichlormethiazide:**

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

**dexamethasone:**

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



## Dexamethasone / Trichlormethiazide Formula- tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

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

- |                                                     |   |                                                                                                                                                                        |
|-----------------------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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: 51 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<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 |
|-----------------------------------------------------|---|--------------------------------------------------------------------------------------------------------|

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

|                                     |   |                                                                                                                                                                                                                                                            |
|-------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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<br>Method: OECD Test Guideline 201 |
| Toxicity to microorganisms          | : | EC50 : > 1.000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>NOEC : 1.000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209                   |
| Toxicity to fish (Chronic toxicity) | : | NOEC: 0,033 mg/l<br>Exposure time: 32 d<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210                                                                                                                                |
| M-Factor (Chronic aquatic toxicity) | : | 1                                                                                                                                                                                                                                                          |

**12.2 Persistence and degradability****Components:****N,N-Dimethylacetamide:**

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

**Benzyl alcohol:**

|                  |   |                                                                                    |
|------------------|---|------------------------------------------------------------------------------------|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 92 - 96 %<br>Exposure time: 14 d |
|------------------|---|------------------------------------------------------------------------------------|

**dexamethasone:**

|                  |   |                                                                                                                        |
|------------------|---|------------------------------------------------------------------------------------------------------------------------|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 50 %<br>Exposure time: 3,54 d<br>Method: OECD Test Guideline 314 |
|------------------|---|------------------------------------------------------------------------------------------------------------------------|

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

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**12.3 Bioaccumulative potential****Components:****Benzyl alcohol:**

Partition coefficient: n-  
octanol/water : log Pow: 1,05

**dexamethasone:**

Partition coefficient: n-  
octanol/water : log Pow: 1,83

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment****Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Other adverse effects****Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

|                        |                                                                                                                                                                                                                                                                                                                      |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.                                                                                                                                                        |

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**SECTION 14: Transport information****14.1 UN number**

|     |                                     |
|-----|-------------------------------------|
| ADN | : Not regulated as a dangerous good |
| ADR | : Not regulated as a dangerous good |

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

|      |   |                                   |
|------|---|-----------------------------------|
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

**14.2 UN proper shipping name**

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

**14.3 Transport hazard class(es)**

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

**14.4 Packing group**

|                  |   |                                   |
|------------------|---|-----------------------------------|
| ADN              | : | Not regulated as a dangerous good |
| ADR              | : | Not regulated as a dangerous good |
| RID              | : | Not regulated as a dangerous good |
| IMDG             | : | Not regulated as a dangerous good |
| IATA (Cargo)     | : | Not regulated as a dangerous good |
| IATA (Passenger) | : | Not regulated as a dangerous good |

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks : Not applicable for product as supplied.

---

**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

AICS : not determined

DSL : not determined

## Dexamethasone / Trichlormethiazide Formula- tion

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

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IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

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

#### Full text of H-Statements

|       |                                                                                   |
|-------|-----------------------------------------------------------------------------------|
| H302  | : Harmful if swallowed.                                                           |
| H312  | : Harmful in contact with skin.                                                   |
| H317  | : May cause an allergic skin reaction.                                            |
| H319  | : Causes serious eye irritation.                                                  |
| H332  | : Harmful if inhaled.                                                             |
| H360D | : May damage the unborn child.                                                    |
| H373  | : May cause damage to organs through prolonged or repeated exposure if swallowed. |
| H410  | : Very toxic to aquatic life with long lasting effects.                           |

#### Full text of other abbreviations

|                   |                                                                                                                                                                      |
|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute Tox.        | : Acute toxicity                                                                                                                                                     |
| Aquatic Chronic   | : Long-term (chronic) aquatic hazard                                                                                                                                 |
| Eye Irrit.        | : Eye irritation                                                                                                                                                     |
| Repr.             | : Reproductive toxicity                                                                                                                                              |
| Skin Sens.        | : Skin sensitisation                                                                                                                                                 |
| STOT RE           | : Specific target organ toxicity - repeated exposure                                                                                                                 |
| 2000/39/EC        | : Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values                                                 |
| 2004/37/EC        | : Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work - Annex III |
| ZA BEI            | : South Africa. The Regulations for Hazardous Chemical Agents, Biological Exposure Indices                                                                           |
| ZA OEL            | : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits                                                                          |
| 2000/39/EC / TWA  | : Limit Value - eight hours                                                                                                                                          |
| 2000/39/EC / STEL | : Short term exposure limit                                                                                                                                          |
| 2004/37/EC / STEL | : Short term exposure limit                                                                                                                                          |
| 2004/37/EC / TWA  | : Long term exposure limit                                                                                                                                           |
| ZA OEL / OEL-RL   | : Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)                                                                     |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration

**Dexamethasone / Trichlormethiazide Formula-  
tion**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 8.1     | 20.06.2025     | 5408280-00016 | Date of first issue: 13.02.2020 |

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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

**Further information**

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

**Classification of the mixture:**

|              |       |
|--------------|-------|
| Eye Irrit. 2 | H319  |
| Skin Sens. 1 | H317  |
| Repr. 1B     | H360D |

**Classification procedure:**

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |

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

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