

## **Dexamethasone / Trichlormethiazide Formula**tion

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.2
 06.04.2024
 5408277-00010
 Date of first issue: 13.02.2020

**Section 1: Identification** 

Product name : Dexamethasone / Trichlormethiazide Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800

CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

Section 2: Hazard identification

**GHS Classification** 

Serious eye damage/eye irri-

tation

Category 2

Skin sensitisation : Category 1

Reproductive toxicity : Category 1

**GHS label elements** 

Hazard pictograms

**!**>

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation. H360D May damage the unborn child.

Precautionary statements : Prevention:



# **Dexamethasone / Trichlormethiazide Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.2 06.04.2024 5408277-00010 Date of first issue: 13.02.2020

P201 Obtain special instructions before use.

P261 Avoid breathing mist or vapours.

P264 Wash skin thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313 IF exposed or concerned: Get medical advice/attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

#### Storage:

P405 Store locked up.

## Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

#### Other hazards which do not result in classification

None known.

#### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)
Propylene glycol	57-55-6	>= 70 -< 90
N,N-Dimethylacetamide	127-19-5	>= 10 -< 20
Benzyl alcohol	100-51-6	>= 1 -< 10
Trichlormethiazide	133-67-5	>= 0.1 -< 1
Dexamethasone	50-02-2	>= 0.025 -< 0.1

#### Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.



# **Dexamethasone / Trichlormethiazide Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.2
 06.04.2024
 5408277-00010
 Date of first issue: 13.02.2020

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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. May cause an allergic skin reaction.

Most important symptoms and effects, both acute and

delaved

Causes serious eye irritation. May damage the unborn child.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

### Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

## Section 6: Accidental release measures

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.



# **Dexamethasone / Trichlormethiazide Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.2 06.04.2024 5408277-00010 Date of first issue: 13.02.2020

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbands.

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 deter-

mine 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 vapours 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 as-

sessment

Keep container tightly closed.

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. 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.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.



# **Dexamethasone / Trichlormethiazide Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.2
 06.04.2024
 5408277-00010
 Date of first issue: 13.02.2020

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

## Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Propylene glycol	57-55-6	WES-TWA (particulate)	10 mg/m3	NZ OEL		
		WES-TWA	150 ppm	NZ OEL		
		(Vapour and particulates)	474 mg/m3			
N,N-Dimethylacetamide	127-19-5	WES-TWA	5 ppm NZ OEL 18 mg/m3			
	Further information: Skin absorption					
		TWA	10 ppm	ACGIH		
Trichlormethiazide	133-67-5	TWA	1 μg/m3 (OEB4)	Internal		
		Wipe limit	10 μg/100 cm2	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 concentration	Basis
N,N-Dimethylacetamide	127-19-5	N- Methyla- cetamide	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 expo-

sure assessment demonstrates exposures outside the rec-



## Dexamethasone / Trichlormethiazide Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.2 06.04.2024 5408277-00010 Date of first issue: 13.02.2020

ommended guidelines, use respiratory protection.

Filter type Hand protection Combined particulates and organic vapour type

Material Chemical-resistant gloves

Remarks Consider double gloving.

Wear safety glasses with side shields or goggles. Eye protection

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

### Section 9: Physical and chemical properties

liquid Appearance

Colour colourless

Odour No data available

Odour Threshold No data available

рΗ No data available

Melting point/freezing point No data available

Initial boiling point and boiling :

range

No data available

No data available Flash point

No data available Evaporation rate

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower : No data available

flammability limit



## Dexamethasone / Trichlormethiazide Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.2 06.04.2024 5408277-00010 Date of first issue: 13.02.2020

No data available Vapour pressure

Relative vapour density No data available

Relative density No data available

No data available Density

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

No data available Viscosity, kinematic

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

No data available Molecular weight

Particle characteristics

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 reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.

products

## **Section 11: Toxicological information**

Inhalation Exposure routes

> Skin contact Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.



# **Dexamethasone / Trichlormethiazide Formula- tion**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.2
 06.04.2024
 5408277-00010
 Date of first issue: 13.02.2020

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

**Components:** 

Propylene glycol:

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

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

N,N-Dimethylacetamide:

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

Acute inhalation toxicity : LC50 (Rat): 2.2 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : Acute toxicity estimate: 1,100 mg/kg

Method: Expert judgement

Remarks: Based on national or regional regulation.

Benzyl alcohol:

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

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Acute dermal toxicity : Acute toxicity estimate: 1,100 mg/kg

Method: Expert judgement

Remarks: Based on national or regional regulation.



## Dexamethasone / Trichlormethiazide Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.2 06.04.2024 5408277-00010 Date of first issue: 13.02.2020

Trichlormethiazide:

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

Symptoms: hyperglycemia

LD50 (Mouse): 2,600 mg/kg

Dexamethasone:

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

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

Acute toxicity (other routes of :

LD50 (Rat): 14 mg/kg

administration) Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Propylene glycol:

Species Rabbit

Method **OECD Test Guideline 404** 

Result No skin irritation

N,N-Dimethylacetamide:

Rabbit **Species** 

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** 



# **Dexamethasone / Trichlormethiazide Formula- tion**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.2
 06.04.2024
 5408277-00010
 Date of first issue: 13.02.2020

N,N-Dimethylacetamide:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Benzyl alcohol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Dexamethasone:

Species : Rabbit

Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

**Components:** 

Propylene glycol:

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

N,N-Dimethylacetamide:

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

Benzyl alcohol:

Assessment : Probability or evidence of skin sensitisation in humans

Remarks : Based on national or regional regulation.

**Chronic toxicity** 

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Propylene glycol:

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

Result: negative



# **Dexamethasone / Trichlormethiazide Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.2 06.04.2024 5408277-00010 Date of first issue: 13.02.2020

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

N,N-Dimethylacetamide:

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

Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Rat

Application Route: Inhalation Method: OECD Test Guideline 478

Result: negative

Benzyl alcohol:

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

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Dexamethasone:

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

Result: negative

Test Type: in vitro 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.



# **Dexamethasone / Trichlormethiazide Formula- tion**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.2
 06.04.2024
 5408277-00010
 Date of first issue: 13.02.2020

**Components:** 

Propylene glycol:

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

N,N-Dimethylacetamide:

Species : Rat

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

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

Reproductive toxicity

May damage the unborn child.

**Components:** 

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

**Application Route: Ingestion** 

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal 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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Inhalation

Result: positive



# **Dexamethasone / Trichlormethiazide Formula- tion**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.2 06.04.2024 5408277-00010 Date of first issue: 13.02.2020

Reproductive toxicity - As-

sessment

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 foetal develop-

ment

Test Type: Embryo-foetal 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 develop-

ment were detected.

Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development

Species: Mouse Application Route: Oral

Early Embryonic Development: NOAEL: 3,000 mg/kg body

weight

Result: No effects on fertility and early embryonic develop-

ment were detected.

Remarks: Based on data from similar materials

Dexamethasone:

Effects on foetal develop-

ment

: Test Type: Development

Species: Mouse

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 6 mg/kg body weight Result: Specific developmental abnormalities, Cleft palate

Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: NOAEL: 0.025 mg/kg body weight

Result: Specific developmental abnormalities

Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: LOAEL: >= 0.062 mg/kg body weight



# **Dexamethasone / Trichlormethiazide Formula- tion**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.2
 06.04.2024
 5408277-00010
 Date of first issue: 13.02.2020

Result: Specific developmental abnormalities

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: >= 0.02 mg/kg body weight

Result: Skeletal and visceral variations, Retardations

Reproductive toxicity - As-

sessment

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:**

## Propylene glycol:

Species : Rat, male

NOAEL : >= 1,700 mg/kg

Application Route : Ingestion

Exposure time : 2 yr

## N,N-Dimethylacetamide:

Species : Rat

NOAEL : 90 mg/m3 LOAEL : 360 mg/m3

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:



# **Dexamethasone / Trichlormethiazide Formula- tion**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.2
 06.04.2024
 5408277-00010
 Date of first issue: 13.02.2020

Species : Rat

NOAEL : 0.0015 mg/kg

Application Route : Oral Exposure time : 7 d Target Organs : Liver

Remarks : Significant toxicity observed in testing

Species : Rat

LOAEL : 0.003 mg/kg

Application Route : Oral Exposure time : 90 d

Target Organs : Blood, Adrenal gland, thymus gland Remarks : Significant toxicity observed in testing

Species : Rat

LOAEL : 0.125 mg/kg

Application Route : Oral
Exposure time : 6 Weeks
Target Organs : Adrenal gland

Remarks : Significant toxicity observed in testing

Species : Rat
LOAEL : 0.4 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Immune system

Remarks : Significant toxicity observed in testing

Species : Dog
LOAEL : 8 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Immune system

Remarks : Significant toxicity observed in testing

## **Aspiration toxicity**

Not classified based on available information.

#### **Experience with human exposure**

## **Components:**

Trichlormethiazide:

General Information : Symptoms: Dizziness, Drowsiness, effects on blood pressure,

Fatigue, Headache, hyperkalemia, hypertension, hypotension

Remarks: The most common side effects are:

Dexamethasone:

Ingestion : Target Organs: Immune system

Target Organs: Adrenal gland

Target Organs: Bone



# **Dexamethasone / Trichlormethiazide Formulation**

Version 4.2

Revision Date: 06.04.2024

SDS Number: 5408277-00010

Date of last issue: 30.09.2023 Date of first issue: 13.02.2020

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 (Chron-

ic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l

Exposure time: 7 d

Toxicity to microorganisms : NOEC (P

NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 h

N,N-Dimethylacetamide:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 500 mg/l

Exposure time: 48 h

Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic

plants

EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC10: > 1,995 mg/l

Exposure time: 30 min

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202



# **Dexamethasone / Trichlormethiazide Formula- tion**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.2 06.04.2024 5408277-00010 Date of first issue: 13.02.2020

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 51 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Dexamethasone:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 56 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.2

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.033 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

M-Factor (Chronic aquatic

toxicity)

: 1

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



# **Dexamethasone / Trichlormethiazide Formulation**

Version Revision Date: 4.2 06.04.2024

SDS Number: 5408277-00010

Date of last issue: 30.09.2023 Date of first issue: 13.02.2020

## 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- : log Pow: -1.07

octanol/water Method: Regulation (EC) No. 440/2008, Annex, A.8

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



# **Dexamethasone / Trichlormethiazide Formula- tion**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 4.2
 06.04.2024
 5408277-00010
 Date of first issue: 13.02.2020

#### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **Section 14: Transport information**

## **International Regulations**

**UNRTDG** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

**IATA-DGR** 

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

IMDG-Code

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

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

## **National Regulations**

NZS 5433

UN number : Not applicable Proper shipping name : Not applicable



## Dexamethasone / Trichlormethiazide Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.2 06.04.2024 5408277-00010 Date of first issue: 13.02.2020

Not applicable Class Subsidiary risk Not applicable Packing group Not applicable Labels Not applicable Not applicable Hazchem Code

Special precautions for user

Not applicable

### **Section 15: Regulatory information**

#### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### **HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

#### **HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

**AICS** not determined

**DSL** not determined

**IECSC** not determined

#### **Section 16: Other information**

**Revision Date** 06.04.2024

**Further information** 

Sources of key data used to

compile the Safety Data

Sheet

Date format

dd.mm.yyyy

Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV) **ACGIH BEI** ACGIH - Biological Exposure Indices (BEI)

NZ OEL New Zealand. Workplace Exposure Standards for Atmospher-

cy, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-



# **Dexamethasone / Trichlormethiazide Formulation**

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ic Contaminants

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

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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

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

NZ / EN