

## Dexamethasone / Trichlormethiazide Formulation

Version 7.0      Revision Date: 2023/09/30      SDS Number: 5408274-00010      Date of last issue: 2023/04/04  
Date of first issue: 2020/02/13

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Dexamethasone / Trichlormethiazide Formulation

#### Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

#### GHS label elements

Hazard pictograms :



Signal word : Danger

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

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P264 Wash skin thoroughly after handling.

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

### Response:

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

P308 + P313 IF exposed or concerned: Get medical 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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Propylene glycol	57-55-6	>= 80 - < 90	2-234
N,N-Dimethylacetamide	127-19-5	16.02	2-723
Benzyl alcohol	100-51-6	>= 1 - < 10	3-1011
Trichlormethiazide	133-67-5	>= 0.1 - < 1	9-461
Dexamethasone	50-02-2	>= 0.025 - < 0.1	
2,6-Di-tert-butyl-p-cresol	128-37-0	>= 0.025 - < 0.1	3-540, 9-1805

## 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

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of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Causes serious eye irritation.  
May damage the unborn child.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

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### 5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

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

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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

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### 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil

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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 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.

### 7. HANDLING AND STORAGE

#### 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.  
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 assessment  
Keep container tightly closed.  
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents

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.

#### Storage

Conditions for safe storage : Keep in properly labelled containers.

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Materials to avoid : Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.  
Do not store with the following product types:  
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	ACL	10 ppm	JP OEL ISHL
		OEL-M	10 ppm 36 mg/m <sup>3</sup>	JP OEL JSOH
Further information: Group 2: Substances presumed to cause reproductive toxicity in humans, Skin absorption, Group 2B: possibly carcinogenic to humans				
Benzyl alcohol	100-51-6	TWA	10 ppm	ACGIH
		OEL-C	25 mg/m <sup>3</sup>	JP OEL JSOH
Further information: Skin sensitizing agent; Group 2 substances which probably induce allergic reactions in humans.				
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		
2,6-Di-tert-butyl-p-cresol	128-37-0	Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
		TWA (Inhalable fraction and vapor)	2 mg/m <sup>3</sup>	ACGIH

#### Biological occupational exposure limits

Components	CAS-No.	Target substance	Biological specimen	Sampling time	Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	N-Methylacetamide	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

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protect products, workers, and the environment.  
Essentially no open handling permitted.  
Use closed processing systems or containment technologies.  
If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

### Personal protective equipment

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	liquid
Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit	:	

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Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Density and / or relative density	:	
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	Not applicable

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**10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reaction	:	Can react with strong oxidizing agents.

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tions  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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**11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

Not classified based on available information.

**Product:**

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

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

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

**Components:****Propylene glycol:**

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

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**N,N-Dimethylacetamide:**

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

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

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



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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

### Trichlormethiazide:

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

### Dexamethasone:

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

### 2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg  
 Method: OECD Test Guideline 401  
 Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
 Method: OECD Test Guideline 402  
 Assessment: The substance or mixture has no acute dermal toxicity

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Propylene glycol:

Species : Rabbit  
 Method : OECD Test Guideline 404  
 Result : No skin irritation

#### N,N-Dimethylacetamide:

Species : Rabbit  
 Result : No skin irritation

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**Benzyl alcohol:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

**Dexamethasone:**

Species : Rabbit  
Result : Mild skin irritation

**2,6-Di-tert-butyl-p-cresol:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****Propylene glycol:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

**N,N-Dimethylacetamide:**

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

**Benzyl alcohol:**

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

**Dexamethasone:**

Species : Rabbit  
Result : Mild eye irritation

**2,6-Di-tert-butyl-p-cresol:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

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### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### 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:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative

##### 2,6-Di-tert-butyl-p-cresol:

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

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Propylene glycol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES)
	Result: negative
	Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)

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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

### **2,6-Di-tert-butyl-p-cresol:**

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

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

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cytogenetic test, chromosomal analysis)  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### Propylene glycol:

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

#### N,N-Dimethylacetamide:

Species : Rat  
 Application Route : inhalation (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

#### 2,6-Di-tert-butyl-p-cresol:

Species : Rat  
 Application Route : Ingestion  
 Exposure time : 22 Months  
 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 development : Test Type: Embryo-foetal development  
 Species: Mouse

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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 development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Inhalation  
 Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

### Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative  
 Remarks: Based on data from similar materials

Effects on foetal development : 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 development were detected.  
 Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development  
 Species: Mouse  
 Application Route: Oral  
 Early Embryonic Development: NOAEL: 3,000 mg/kg body weight  
 Result: No effects on fertility and early embryonic development were detected.  
 Remarks: Based on data from similar materials

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### Dexamethasone:

Effects on foetal development : Test Type: Development  
Species: Mouse  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 6 mg/kg body weight  
Result: Specific developmental abnormalities, Cleft palate

Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: NOAEL: 0.025 mg/kg body weight  
Result: Specific developmental abnormalities

Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL:  $\geq$  0.062 mg/kg body weight  
Result: Specific developmental abnormalities

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL:  $\geq$  0.02 mg/kg body weight  
Result: Skeletal and visceral variations, Retardations

Reproductive toxicity - Assessment : May damage the unborn child.

### 2,6-Di-tert-butyl-p-cresol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### 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.

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### 2,6-Di-tert-butyl-p-cresol:

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

### 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:

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



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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

### 2,6-Di-tert-butyl-p-cresol:

Species : Rat  
 NOAEL : 25 mg/kg  
 Application Route : Ingestion  
 Exposure time : 22 Months

### 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

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### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

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

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h

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

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

##### **Benzyl alcohol:**

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770

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plants mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

### Dexamethasone:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 56 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.2 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.033 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

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

### 2,6-Di-tert-butyl-p-cresol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0.57 mg/l  
Exposure time: 96 h  
Method: Directive 67/548/EEC, Annex V, C.1.

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Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0.48 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l Exposure time: 30 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.316 mg/l Exposure time: 21 d
M-Factor (Chronic aquatic toxicity)	:	1
Toxicity to microorganisms	:	EC50: > 10,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

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

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F
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##### **N,N-Dimethylacetamide:**

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 70 % Exposure time: 28 d Remarks: The 10 day time window criterion is not fulfilled.
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##### **Benzyl alcohol:**

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

### Dexamethasone:

|| Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 50 %  
Exposure time: 3.54 d  
Method: OECD Test Guideline 314

### 2,6-Di-tert-butyl-p-cresol:

|| Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 4.5 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

### Bioaccumulative potential

#### Components:

#### Propylene glycol:

|| Partition coefficient: n-octanol/water : log Pow: -1.07  
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

#### 2,6-Di-tert-butyl-p-cresol:

|| Bioaccumulation : Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): 330 - 1,800

|| Partition coefficient: n-octanol/water : log Pow: 5.1

#### Mobility in soil

No data available

#### Hazardous to the ozone layer

Not applicable

#### Other adverse effects

No data available

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## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

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Contaminated packaging : Do not dispose of waste into sewer.  
 : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
 If not otherwise specified: Dispose of as unused product.

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### 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

##### 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 aircraft) : Not applicable  
 Packing instruction (passenger aircraft) : Not applicable

##### IMDG-Code

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

Refer to section 15 for specific national regulation.

#### Special precautions for user

Not applicable

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## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Propane-1,2-diol	106
2,6-Di-tert-butyl-4-methylphenol	64

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### Substances Prevented From Impairment of Health

Chemical name
N,N-dimethylacetamide

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
propane-1,2-diol	>=80 - <90	From April 1st, 2025
N,N-Dimethylacetamide	>=10 - <20	-
Benzyl alcohol	>=1 - <10	-

#### Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
propane-1,2-diol	From April 1st, 2025
N,N-Dimethylacetamide	-
benzyl alcohol	-

#### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

#### Ordinance on Prevention of Lead Poisoning

Not applicable

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### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

### Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

### Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

### Poisonous and Deleterious Substances Control Law

Not applicable

### Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

### Class I Designated Chemical Substances

Chemical name	Administration number	Concentration (%)
N,N-Dimethylacetamide	213	16

### High Pressure Gas Safety Act

Not applicable

### Explosive Control Law

Not applicable

### Vessel Safety Law

Not regulated as a dangerous good

### Aviation Law

Not regulated as a dangerous good

### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Not classified as marine pollutant

### Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

### Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined



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### 16. OTHER INFORMATION

#### 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/>

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

Date format : yyyy/mm/dd

#### Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	: ACGIH - Biological Exposure Indices (BEI)
JP OEL ISHL	: Japan. Administrative Control Levels
JP OEL JSOH	: Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits
ACGIH / TWA	: 8-hour, time-weighted average
JP OEL ISHL / ACL	: Administrative Control level
JP OEL JSOH / OEL-M	: Occupational Exposure Limit-Mean
JP OEL JSOH / OEL-C	: Occupational Exposure Limit-Ceiling

AIRC - 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; KECl - 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 Tem-

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perature; 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.

JP / EN