

**Prednisolone / Chloramphenicol Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
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**1. PRODUCT AND COMPANY IDENTIFICATION**

Chemical product name : Prednisolone / Chloramphenicol Formulation

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

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

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**

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B

**GHS label elements**

Hazard pictograms :



Signal word : Danger

Hazard statements : H351 Suspected of causing cancer.  
H360 May damage fertility or 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.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/

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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**

Important symptoms and out- : Dust contact with the eyes can lead to mechanical irritation.  
lines of the emergency as- Contact with dust can cause mechanical irritation or drying of  
sumed the skin.  
May form combustible dust concentrations in air during pro-  
cessing, handling or other means.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Propylene glycol	57-55-6	$\geq 1 - < 10$	2-234
Chloramphenicol	56-75-7	$\geq 1 - < 10$	-
Sulfuric acid, mono-C16-18-alkyl esters, sodium salts	68955-20-4	$\geq 0.25 - < 1$	2-1679
prednisolone	50-24-8	$\geq 0.1 - < 0.25$	-
Tetradecanol	112-72-1	$\geq 0.025 - < 0.1$	2-217, 2-3704
Dodecan-1-ol	112-53-8	$\geq 0.0025 - < 0.025$	2-217
Basic phenylmercury nitrate	8003-05-2	0.002	-

**4. FIRST AID MEASURES**

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

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

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.

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In case of eye contact	: Thoroughly clean shoes before reuse. If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
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	: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. Suspected of causing cancer. May damage fertility or 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.

**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
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.

**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. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages

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cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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**7. HANDLING AND STORAGE****Handling**

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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 dust.  
Do not breathe vapours.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
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

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use of administrative controls.

### Storage

- Conditions for safe storage : Keep in properly labelled containers.  
 Store locked up.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents
- 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 / Concentration standard / Permissible concentration	Basis
Chloramphenicol	56-75-7	TWA	300 µg/m <sup>3</sup> (OEB 2)	
prednisolone	50-24-8	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Basic phenylmercury nitrate	8003-05-2	TWA	0.1 mg/m <sup>3</sup> (Mercury)	ACGIH

### Biological occupational exposure limits

Components	CAS-No.	Target substance	Biological specimen	Sampling time	Permissible concentration	Basis
Basic phenylmercury nitrate	8003-05-2	total inorganic mercury (Mercury)	Urine	Not critical	35 µg/g creatinine	JSOH

- 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.  
 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
 Minimize open handling.

### 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

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## 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.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : cream

Colour : No data available

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) : May form combustible dust concentrations in air during processing, handling or other means.

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

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

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**10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form combustible dust concentrations in air during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
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
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**Acute toxicity**

Not classified based on available information.

**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

**Chloramphenicol:**

Acute oral toxicity	: LD50 Oral (Rat): 2,500 mg/kg
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**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

Acute oral toxicity	: LD50 (Rat): 4,010 mg/kg Remarks: Based on data from similar materials
Acute dermal toxicity	: LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Remarks: Based on data from similar materials

**prednisolone:**

Acute oral toxicity	: LD50 (Mouse): 1,680 mg/kg LD50 (Rat): > 3,857 mg/kg
Acute inhalation toxicity	: Remarks: No data available
Acute dermal toxicity	: Remarks: No data available
Acute toxicity (other routes of administration)	: LD50 (Rat): 147 mg/kg Application Route: Subcutaneous LD50 (Mouse): 767 mg/kg Application Route: Intraperitoneal

**Tetradecanol:**

Acute oral toxicity	: LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 401 Assessment: The substance or mixture has no acute oral toxicity
Acute inhalation toxicity	: LC50 (Rat): > 1.5 mg/l Exposure time: 1 h



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Test atmosphere: vapour  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

**Dodecan-1-ol:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 12 mg/l  
Exposure time: 6 h  
Test atmosphere: vapour  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

**Basic phenylmercury nitrate:**

Acute oral toxicity : LD50 (Mouse): > 50 - 300 mg/kg  
Remarks: Based on data from similar materials

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

**Skin corrosion/irritation**

Not classified based on available information.

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

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

**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Skin irritation  
Remarks : Based on data from similar materials

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Remarks : No data available

**Tetradecanol:**

Species : Human  
Result : No skin irritation

**Dodecan-1-ol:**

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Species	: Human
Result	: No skin irritation

**Basic phenylmercury nitrate:**

Result	: Corrosive after 4 hours or less of exposure
Remarks	: Based on data from similar materials

**Serious eye damage/eye irritation**

Not classified based on available information.

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

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

**Chloramphenicol:**

Remarks	: Mild eye irritation
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**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

Species	: Rabbit
Result	: Irreversible effects on the eye
Method	: OECD Test Guideline 405
Remarks	: Based on data from similar materials

**prednisolone:**

Remarks	: No data available
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**Tetradecanol:**

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

**Dodecan-1-ol:**

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

**Basic phenylmercury nitrate:**

Result	: Irreversible effects on the eye
Remarks	: Based on skin corrosivity.

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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

**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

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

**prednisolone:**

Remarks	: No data available
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**Tetradecanol:**

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

**Dodecan-1-ol:**

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

**Germ cell mutagenicity**

Not classified based on available information.

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

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

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Genotoxicity in vivo	Method: OECD Test Guideline 473
	Result: negative
:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
	Species: Mouse
	Application Route: Intraperitoneal injection
	Result: negative

**Chloramphenicol:**

Genotoxicity in vitro	Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
	Test system: human diploid fibroblasts
	Result: positive

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: positive

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

Test Type: Chromosome aberration test in vitro
Test system: mammalian cells
Result: positive

Genotoxicity in vivo	Test Type: Chromosomal aberration
	Species: Mouse
	Cell type: Bone marrow
	Result: positive

Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Result: negative

Test Type: Micronucleus test
Species: Rat
Cell type: Bone marrow
Result: negative

**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

Genotoxicity in vitro	Test Type: Bacterial reverse mutation assay (AMES)
	Method: OECD Test Guideline 471
	Result: negative

**prednisolone:**

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

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Genotoxicity in vivo	:	Test Type: Mouse Lymphoma Result: negative
	:	Test Type: sister chromatid exchange assay Result: negative
	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Application Route: Oral Result: negative
	:	Test Type: sister chromatid exchange assay Species: Humans Result: negative

**Tetradecanol:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
	:	Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials
	:	Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials
	:	

**Dodecan-1-ol:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
	:	Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials
	:	Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials
	:	
Genotoxicity in vivo	:	Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative

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**II****Carcinogenicity**

Suspected of causing cancer.

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

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

**Chloramphenicol:**

Remarks	: IARC: (International Agency for Research on Cancer)
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Carcinogenicity - Assessment	: Limited evidence of carcinogenicity in animal studies
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**prednisolone:**

Species	: Rat
Application Route	: Oral
Exposure time	: 18 Months
Result	: negative

**Reproductive toxicity**

May damage fertility or the unborn child.

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

Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative
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Effects on foetal development	: Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative
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**Chloramphenicol:**

Effects on foetal development	: Species: Monkey, female Result: No significant adverse effects were reported  Species: Mouse Developmental Toxicity: LOAEL: 500 mg/kg body weight Result: Embryo-foetal toxicity, Fetal growth retardation  Species: Rat Developmental Toxicity: LOAEL: 500 - 2,000 mg/kg body
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		weight Result: Embryo-foetal toxicity, Fetal growth retardation, Teratogenic effects
		Species: Rabbit Developmental Toxicity: LOAEL: 1,000 mg/kg body weight Result: Embryo-foetal toxicity, Fetal growth retardation
Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments

**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

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

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Subcutaneous Fertility: NOAEL: 1 mg/kg body weight Result: No effects on fertility
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Mouse Application Route: Oral Developmental Toxicity: LOAEL: 0.5 mg/kg body weight Result: Malformations were observed., Cleft palate
		Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: decreased blood formation
		Species: Rat Application Route: Subcutaneous Developmental Toxicity: NOAEL: 25 mg/kg body weight Result: No effects on foetal development
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.

**Dodecan-1-ol:**

Effects on fertility	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative
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Effects on foetal development	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative
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**Basic phenylmercury nitrate:**

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Mouse Application Route: Intraperitoneal injection Result: positive Remarks: Based on data from similar materials
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Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on development, based on animal experiments.
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**STOT - single exposure**

Not classified based on available information.

**Components:****Chloramphenicol:**

Exposure routes	:	Oral
Target Organs	:	Blood, Bone marrow

**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

Assessment	:	May cause respiratory irritation.
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**STOT - repeated exposure**

Not classified based on available information.

**Components:****Chloramphenicol:**

Exposure routes	:	Oral, Inhalation
Target Organs	:	Blood, Bone marrow, Liver

**prednisolone:**

Target Organs	:	Bone marrow, Adrenal gland, Liver
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

**Basic phenylmercury nitrate:**

Exposure routes	:	Oral
Target Organs	:	Kidney
Assessment	:	Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.



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**Repeated dose toxicity****Components:****Propylene glycol:**

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

**Chloramphenicol:**

Species	: Dog
Target Organs	: Blood, Bone marrow
Symptoms	: decrease in appetite, Reduced body weight

**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

Species	: Rat
NOAEL	: 428 mg/kg
LOAEL	: 970 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

**prednisolone:**

Species	: Rat
LOAEL	: 0.6 mg/kg
Application Route	: Oral
Exposure time	: 63 Days
Target Organs	: Bone marrow

Species	: Dog
LOAEL	: 2.5 mg/kg
Application Route	: Oral
Exposure time	: 6 Weeks
Target Organs	: Adrenal gland

Species	: Rabbit
LOAEL	: 1 mg/kg
Application Route	: Oral
Exposure time	: 24 Weeks
Target Organs	: Liver

**Dodecan-1-ol:**

Species	: Rat
NOAEL	: $> 2,000$ mg/kg
Application Route	: Ingestion
Exposure time	: 41 - 45 Days

**Basic phenylmercury nitrate:**

Species	: Rat
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NOAEL	: < 1.25 mg/kg
Application Route	: Ingestion
Exposure time	: 2 yr
Remarks	: Based on data from similar materials

**Aspiration toxicity**

Not classified based on available information.

**Components:****Dodecan-1-ol:**

The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

**Experience with human exposure****Components:****Chloramphenicol:**

General Information	: Target Organs: Blood
	Target Organs: Bone marrow
	Symptoms: aplastic anemia, confusion, Diarrhoea, Fever, Headache, Nausea, Vomiting

**prednisolone:**

Ingestion	: Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities
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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 (Chron-	: NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d

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ic toxicity)

Toxicity to microorganisms : NOEC (*Pseudomonas putida*): > 20,000 mg/l  
Exposure time: 18 h

**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

Toxicity to fish : LC50 (*Danio rerio* (zebra fish)): 5.2 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 2.8 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (*Desmodesmus subspicatus* (green algae)): 34 mg/l  
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Ceriodaphnia dubia* (water flea)): 0.204 mg/l  
Exposure time: 7 d  
Remarks: Based on data from similar materials

Toxicity to microorganisms : NOEC (*Pseudomonas putida*): 550 mg/l  
Exposure time: 18 h

**prednisolone:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 85 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : NOEC (*Pseudokirchneriella subcapitata* (green algae)): 160 mg/l  
Exposure time: 72 h

EC50 (*Pseudokirchneriella subcapitata* (green algae)): > 160 mg/l  
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Ceriodaphnia dubia* (water flea)): 0.23 mg/l  
Exposure time: 7 d

**Tetradecanol:**

Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): > 1 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 3.2 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EL50 (*Desmodesmus subspicatus* (green algae)): > 10 mg/l  
Exposure time: 96 h

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	Test substance: Water Accommodated Fraction
	EL10 (Desmodesmus subspicatus (green algae)): 2.9 mg/l
	Exposure time: 96 h
	Test substance: Water Accommodated Fraction
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: EC10 (Daphnia magna (Water flea)): 0.0063 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	: 1
<b>Dodecan-1-ol:</b>	
Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): 1.01 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0.765 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: ErC50 (Desmodesmus subspicatus (green algae)): 0.66 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC (Desmodesmus subspicatus (green algae)): 0.085 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 1
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: EC10 (Daphnia magna (Water flea)): 0.013 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	: EC0 (Pseudomonas putida): > 10,000 mg/l Exposure time: 30 min

**Basic phenylmercury nitrate:**

Toxicity to fish	: EC50 (Oncorhynchus mykiss (rainbow trout)): > 0.001 - 0.01 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 0.001 - 0.01 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials

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EC10 (*Pseudokirchneriella subcapitata* (green algae)): > 0.01 - 0.1 mg/l  
Exposure time: 72 h  
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 100

Toxicity to fish (Chronic toxicity) : NOEC (*Pimephales promelas* (fathead minnow)): > 0.0001 - 0.001 mg/l  
Exposure time: 32 d  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Mysidopsis bahia* (opossum shrimp)): > 0.001 - 0.01 mg/l  
Exposure time: 35 d  
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 10

Toxicity to microorganisms : NOEC (Bacteria): > 0.001 - 0.01 mg/l  
Exposure time: 18 h  
Remarks: Based on data from similar materials

**Persistence and degradability****Components:****Propylene glycol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 77 %  
Exposure time: 30 d  
Method: OECD Test Guideline 301D

**Tetradecanol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 %  
Exposure time: 28 d

**Dodecan-1-ol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 79 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D

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**II****Basic phenylmercury nitrate:**

Biodegradability	:	Result: Readily biodegradable. Remarks: Based on data from similar materials
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**Bioaccumulative potential****Components:****Propylene glycol:**

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

Partition coefficient: n-octanol/water	:	log Pow: 1.46
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**Tetradecanol:**

Partition coefficient: n-octanol/water	:	log Pow: 5.5
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**Dodecan-1-ol:**

Partition coefficient: n-octanol/water	:	log Pow: $\geq 4$ Remarks: Based on data from similar materials
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**Basic phenylmercury nitrate:**

Partition coefficient: n-octanol/water	:	log Pow: 1.27
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**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. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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**14. TRANSPORT INFORMATION****International Regulations**

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**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 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

**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
Sodium alkyl(C=8-18) sulfate	214
Alkanol(C=10-16) (only the substances that contain any of C=11-14	171

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Components)

**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**

Not applicable

**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**

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

Chemical name	Concentration (%)	Remarks
Propylene glycol	$\geq 1$ - $< 10$	From April 1st, 2025
2,2-dichloro-N-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]acetamide	$\geq 1$ - $< 10$	-

**Substances Subject to be Indicated Names**

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

Chemical name	Remarks
Propylene glycol	From April 1st, 2025
2,2-dichloro-N-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]acetamide	-

**Skin and Eye Damage Substances (ISHL MO Art. 594-2)**

Not applicable

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Chemical name
2,2-dichloro-N-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]acetamide

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

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable



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**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**

Poisonous substance

Chemical name	Cabinet Order Number
Mercury compounds and preparations containing them	17

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

Not applicable

**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 : Not classified as noxious liquid substance

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

**16. OTHER INFORMATION**

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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**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)  
JSOH : Occupational exposure limits based on biological monitoring (JSOH).

ACGIH / TWA : 8-hour, 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

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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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