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 6.0
 28.09.2024
 9374471-00008
 Date of first issue: 27.08.2021

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Prednisolone / Chloramphenicol Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

## 1.4 Emergency telephone number

+1-908-423-6000

## **SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Carcinogenicity, Category 2 H351: Suspected of causing cancer.

Reproductive toxicity, Category 1B H360: May damage fertility or the unborn child.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms

Signal word : Danger

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Hazard statements : H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

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

attention.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Chloramphenicol

#### 2.3 Other hazards

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

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

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

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

### Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Chloramphenicol	56-75-7	Carc. 2; H351	>= 1 - < 10
	200-287-4	Repr. 1B; H360	
prednisolone	50-24-8	Acute Tox. 4; H302	>= 0.1 - < 0.25
	200-021-7	Repr. 2; H361d	
		STOT RE 1; H372	
		(Bone marrow,	
		Adrenal gland, Liv-	
		er)	
		Aquatic Chronic 2;	
		H411	
Basic phenylmercury nitrate	8003-05-2	Acute Tox. 3; H301	>= 0.0002 - <
		Skin Corr. 1; H314	0.0025
	080-008-00-9	Eye Dam. 1; H318	
		Repr. 1B; H360D	
		STOT RE 1; H372	
		(Kidney)	
		Aquatic Acute 1;	

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			H400 Aquatic Chronic 1; H410 ————————————————————————————————————	
Subst	tances with a workpla	ce exposure limit :		
Propy	rlene glycol	57-55-6 200-338-0	>=1-<	10

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

## 4.1 Description of first aid measures

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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

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

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

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

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : 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.

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

Risks : Suspected of causing cancer.

May damage fertility or the unborn child.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

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4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

**SECTION 5: Firefighting measures** 

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

: Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides

ucts

5.3 Advice for firefighters

Special protective equipment:

for firefighters

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

Use personal protective equipment.

Specific extinguishing 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.

**SECTION 6: Accidental release measures** 

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions Use personal protective equipment.

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

tective equipment recommendations (see section 8).

6.2 Environmental precautions

**Environmental precautions** Avoid release to the environment.

> Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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## 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 6.4 Reference to other sections

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

## **SECTION 7: Handling and storage**

### 7.1 Precautions for safe 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 as-

sessment

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.

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 contami-

nated 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.

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## 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

**Explosives** 

7.3 Specific end use(s)

Specific use(s) : No data available

## **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

## **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propylene glycol	57-55-6	TWA (Total va- pour and parti- cles)	150 ppm 474 mg/m3	GB EH40
		TWA (particles)	10 mg/m3	GB EH40
Chloramphenicol	56-75-7	TWA	300 μg/m3 (OEB 2)	
	Further information: Eye			
prednisolone	50-24-8	TWA	10 μg/m3 (OEB 3)	Internal
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal

## **Derived No Effect Level (DNEL)**

Substance name	End Use	Exposure routes	Potential health effects Value	
Propylene glycol	Workers	Inhalation	Long-term local ef- fects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local effects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
Hexadecan-1-ol	Workers	Inhalation	Long-term systemic effects	220 mg/m3
	Workers	Inhalation	Acute systemic effects	220 mg/m3
	Workers	Skin contact	Long-term systemic effects	125 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	125 mg/kg bw/day

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	Consumers	Inhalation	Long-term systemic effects	65 mg/m3
	Consumers	Inhalation	Acute systemic effects	65 mg/m3
	Consumers	Skin contact	Long-term systemic effects	75 mg/kg bw/day
	Consumers	Ingestion		75 mg/kg bw/day
Octadecan-1-ol	Workers	Inhalation	Long-term systemic effects	389 mg/m3
	Workers	Inhalation	Long-term local ef- fects	224 mg/m3
	Workers	Skin contact	Long-term systemic effects	110 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	96 mg/m3
	Consumers	Skin contact	Long-term systemic effects	55 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	55 mg/kg bw/day

## **Predicted No Effect Concentration (PNEC)**

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)
Hexadecan-1-ol	Fresh water sediment	30 mg/kg dry weight (d.w.)
	Marine sediment	3 mg/kg dry weight (d.w.)
	Soil	5.8 mg/kg dry weight (d.w.)
Octadecan-1-ol	Fresh water sediment	56.6 mg/kg dry weight (d.w.)
	Marine sediment	5.66 mg/kg dry weight (d.w.)
	Soil	11.3 mg/kg dry weight (d.w.)

## 8.2 Exposure controls

### **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.

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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

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

#### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Appearance : cream

Colour : No data available
Odour : No data available
Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form combustible dust concentrations in air during pro-

cessing, handling or other means.

Upper explosion limit / Upper

flammability limit

No data available

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Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility
Partition coefficient: n-

octanol/water

No data available Not applicable

riot applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : Not applicable

Molecular weight : No data available

Particle size : No data available

## **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

## 10.2 Chemical stability

Stable under normal conditions.

## 10.3 Possibility of hazardous reactions

Hazardous reactions : May form combustible dust concentrations in air during pro-

cessing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

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10.5 Incompatible materials

Materials to avoid Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

**SECTION 11: Toxicological information** 

11.1 Information on toxicological effects

Information on likely routes of: Inhalation

Skin contact exposure Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

**Components:** 

Chloramphenicol:

Acute oral toxicity LD50 Oral (Rat): 2,500 mg/kg

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 : LD50 (Rat): 147 mg/kg

administration)

Application Route: Subcutaneous

LD50 (Mouse): 767 mg/kg

Application Route: Intraperitoneal

Basic phenylmercury nitrate:

Acute oral toxicity LD50 (Mouse): > 50 - 300 mg/kg

Remarks: Based on data from similar materials

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

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

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

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

prednisolone:

Remarks : No data available

Basic phenylmercury nitrate:

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

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Chloramphenicol:

Remarks : Mild eye irritation

prednisolone:

Remarks : No data available

Basic phenylmercury nitrate:

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

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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**Components:** 

prednisolone:

Remarks : No data available

Propylene glycol:

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

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

**Chloramphenicol:** 

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro) Test system: human diploid fibroblasts

Result: positive

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis 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

prednisolone:

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

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Result: negative

Test Type: Mouse Lymphoma

Result: negative

Test Type: sister chromatid exchange assay

Result: negative

Genotoxicity in vivo : 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

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) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Carcinogenicity

Suspected of causing cancer.

**Components:** 

**Chloramphenicol:** 

Remarks : IARC: (International Agency for Research on Cancer)

Carcinogenicity - Assess-

ment

Limited evidence of carcinogenicity in animal studies

prednisolone:

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

Propylene glycol:

Species : Rat

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

## Reproductive toxicity

May damage fertility or the unborn child.

### **Components:**

## **Chloramphenicol:**

Effects on foetal develop-

ment

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

weight

Result: Embryo-foetal toxicity, Fetal growth retardation, Tera-

togenic effects

Species: Rabbit

Developmental Toxicity: LOAEL: 1,000 mg/kg body weight Result: Embryo-foetal toxicity, Fetal growth retardation

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on sexual function and fertil-

ity, and/or on development, based on animal experiments

#### 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 develop-

ment

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

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Result: No effects on foetal development

Reproductive toxicity - As-

sessment

: Some evidence of adverse effects on development, based on

animal experiments.

Basic phenylmercury nitrate:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Intraperitoneal injection

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

: Clear evidence of adverse effects on development, based on

animal experiments.

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

#### STOT - single exposure

Not classified based on available information.

#### **Components:**

#### Chloramphenicol:

Exposure routes : Oral

Target Organs : Blood, Bone marrow

#### 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.

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#### Basic phenylmercury nitrate:

Exposure routes Oral Target Organs Kidney

Assessment Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

#### Repeated dose toxicity

#### **Components:**

## **Chloramphenicol:**

Species Dog

Target Organs Blood, Bone marrow

Symptoms decrease in appetite, Reduced body weight

### prednisolone:

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

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

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

## Basic phenylmercury nitrate:

Species : Rat

NOAEL : < 1.25 mg

Application Route : Ingestion

Exposure time : 2 vr : < 1.25 mg/kg

Exposure time : 2 yr

Based on data from similar materials Remarks

### Propylene glycol:

: Rat, male Species NOAEL : >= 1,700 mg/kg. >= 1,700 : Ingestion Application Route Exposure time : 2 yr

### **Aspiration toxicity**

Not classified based on available information.

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#### **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 reten-

tion, subcutaneous bleeding, striae, skin atrophy, menstrual

irregularities

## **SECTION 12: Ecological information**

## 12.1 Toxicity

## **Components:**

#### prednisolone:

aquatic invertebrates

Toxicity to daphnia and other : 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

Exposure time: 72 h

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.23 mg/l Exposure time: 7 d

Species: Ceriodaphnia dubia (water flea)

### 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 tox-

icity)

NOEC (Bacteria): > 0.001 - 0.01 mg/l Toxicity to microorganisms

100

Exposure time: 18 h

Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox-

icity)

NOEC: > 0.0001 - 0.001 mg/l

NOEC: > 0.001 - 0.01 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow) Remarks: Based on data from similar materials

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

Exposure time: 35 d

Species: Mysidopsis bahia (opossum shrimp) Remarks: Based on data from similar materials

M-Factor (Chronic aquatic

toxicity)

10

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

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

Exposure time: 18 h

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

NOEC: 13,020 mg/l Exposure time: 7 d

ic toxicity) Species: Ceriodaphnia dubia (water flea)

## 12.2 Persistence and degradability

### **Components:**

Basic phenylmercury nitrate:

Biodegradability Result: Readily biodegradable.

Remarks: Based on data from similar materials

### Propylene glycol:

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

#### 12.3 Bioaccumulative potential

### **Components:**

prednisolone:

Partition coefficient: n-

octanol/water

log Pow: 1.46

Basic phenylmercury nitrate:

Partition coefficient: n-

octanol/water

log Pow: 1.27

Propylene glycol:

Partition coefficient: n-

: log Pow: -1.07

octanol/water

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

#### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

#### 12.6 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

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.

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### **SECTION 14: Transport information**

#### 14.1 UN number

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

14.2 UN proper shipping name

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

#### 14.3 Transport hazard class(es)

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

## 14.4 Packing group

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

#### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

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

Remarks : Not applicable for product as supplied.

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## **SECTION 15: Regulatory information**

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the fol-

lowing entries should be considered: Number on list 18: Basic phenylmer-

cury nitrate

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

Not applicable

Not applicable

: Not applicable

Not applicable

Not applicable

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) on substances that deplete the ozone

layer

UK REACH List of substances subject to authorisation

(Annex XIV)

GB Export and import of hazardous chemicals - Prior

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Not applicable

## Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

#### **Full text of H-Statements**

H301 : Toxic if swallowed. H302 : Harmful if swallowed.

H314 : Causes severe skin burns and eye damage.

H318 : Causes serious eye damage. H351 : Suspected of causing cancer.

H360 : May damage fertility or the unborn child.

H360D : May damage the unborn child.

H361d : Suspected of damaging the unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.H411 : Toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard Aquatic Chronic : Long-term (chronic) aquatic hazard

Carc. : Carcinogenicity
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity

Skin Corr. : Skin corrosion

STOT RE : Specific target organ toxicity - repeated exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Ef-

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fect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sources of key data used to : compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

#### Classification of the mixture:

#### Classification procedure:

Carc. 2 H351 Calculation method Repr. 1B H360 Calculation method

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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.

GB / EN