SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Prednisolone / Chloramphenicol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.0	14.04.2025	5723174-00012	Date of first issue: 23.04.2020

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 Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

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)

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.
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.

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

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

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. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Chloramphenicol	56-75-7 200-287-4	Carc. 2; H351 Repr. 1B; H360	>= 1 - < 10
prednisolone	50-24-8 200-021-7	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow, Adrenal gland, Liver) Aquatic Chronic 2;	>= 0,1 - < 0,25

		H411	
Basic phenylmercury nitrate	8003-05-2 080-008-00-9	Acute Tox. 3; H301 Skin Corr. 1; H314 Eye Dam. 1; H318 Repr. 1B; H360D STOT RE 1; H372 (Kidney) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH071 _____ M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 10 _____ Acute toxicity estimate Acute oral toxicity: 100 mg/kg	>= 0,0002 - < 0,0025

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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 products : Carbon oxides

5.3 Advice for firefighters

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

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : 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.

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 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.

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.

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	25 ppm 79 mg/m3	FOR-2011-12-06-1358
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 cm²	Internal
Basic phenylmercury nitrate	8003-05-2	TWA	0,02 mg/m3 (Mercury)	FOR-2011-12-06-1358
	Further information: Substances considered to be reprotoxic, Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin			

Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
Basic phenylmercury nitrate	8003-05-2	Mercury (Mercury): 30 µg/g creatinine (Urine)		AN 361

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	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
	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 effects	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) according to Regulation (EC) No. 1907/2006

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.
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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter should conform to NS 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

Physical state	:	cream
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
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
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	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
Relative density	:	No data available
Density	:	No data available

Relative vapour density	:	Not applicable
Particle characteristics		
Particle size	:	No data available

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	Not applicable
Molecular weight	:	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 processing, 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.

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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure	:	Inhalation Skin contact 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 administration)	:	LD50 (Rat): 147 mg/kg 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
Acute inhalation toxicity	:	Assessment: Corrosive to the respiratory tract.

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

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.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

prednisolone:

Remarks	:	No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

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

prednisolone:

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

Carcinogenicity

Suspected of causing cancer.

Components:

Chloramphenicol:

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

prednisolone:

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

Reproductive toxicity

May damage fertility or the unborn child.

Components:

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 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

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.

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

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.

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.

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	:	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

Basic phenylmercury nitrate:

Species	:	Rat
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.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

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

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

prednisolone:

Toxicity to daphnia and other	:	EC50 (Daphnia magna (Water flea)): > 85 mg/l

aquatic invertebrates		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: 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 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 microorganisms	:	NOEC (Bacteria): > 0,001 - 0,01 mg/l Exposure time: 18 h Remarks: Based on data from similar materials
Toxicity to fish (Chronic toxicity)	:	NOEC: > 0,0001 - 0,001 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 (Chronic toxicity)	:	NOEC: > 0,001 - 0,01 mg/l Exposure time: 35 d Species: Mysidopsis bahia (opossum shrimp) Remarks: Based on data from similar materials
M-Factor (Chronic aquatic	:	10

toxicity)

12.2 Persistence and degradability

Components:

Basic phenylmercury nitrate:

Biodegradability	:	Result: Readily biodegradable. Remarks: Based on data from similar materials

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

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 Endocrine disrupting properties

Product:

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

12.7 Other adverse effects

No data available

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.

Contaminated packaging	:	Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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.

SECTION 14: Transport information

14.1 UN number or ID 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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 18: Basic phenylmercury nitrate

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

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.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.
Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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.

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.
EUH071	:	Corrosive to the respiratory tract.

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
AN 361	:	Norway. Directive on measures and limit values for physical and chemical factors in the work environment (biological limit values).
FOR-2011-12-06-1358	:	Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	:	Long term exposure limit

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

Further information

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

Classification of the mixture:		**Classification procedure:**
Carc. 2	H351	Calculation method
Repr. 1B	H360	Calculation method

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

NO / EN