SAFETY DATA SHEET

Prednisolone / Chloramphenicol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.7	30.09.2023	5710726-00008	Date of first issue: 23.04.2020

SECTION 1. IDENTIFICATION

Product name : Prednisolone / Chloramphenicol Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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/ 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

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

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Chloramphenicol	56-75-7	>= 1 -< 5
prednisolone	50-24-8	>= 0,1 -< 0,25
Basic phenylmercury nitrate	8003-05-2	>= 0,0003 -< 0,0025

SECTION 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.
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.

Most important symptoms and effects, both acute and delayed : 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.

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

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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 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.

SECTION 7. HANDLING AND STORAGE

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 vapors.
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.

Conditions for safe storage : Keep in properly labeled 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
Self-reactive substances and mixtures
Organic peroxides
Explosives

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Chloramphenicol	56-75-7	TWA	300 µg/m3 (OEB 2)	
prednisolone	50-24-8	TWA	10 µg/m3 (OEB 3)	Internal
		Wipe limit	100 µg/100 cm²	Internal
Basic phenylmercury nitrate	8003-05-2	CMP	0,1 mg/m³ (Mercury)	AR OEL
	Further information: Skin			
		TWA	0,1 mg/m³ (Mercury)	ACGIH

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 vapor type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	cream
Color	:	No data available
Odor	:	No data available
Odor 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 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
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition 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.
Molecular weight	:	No data available
Particle size	:	No data available

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure | Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

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 fetal development : Species: Monkey, female

Result: No significant adverse effects were reported

Species: Mouse
Developmental Toxicity: LOAEL: 500 mg/kg body weight
Result: Embryo-fetal toxicity., Fetal growth retardation

Species: Rat
Developmental Toxicity: LOAEL: 500 - 2.000 mg/kg body weight
Result: Embryo-fetal toxicity., Fetal growth retardation, Teratogenic effects.

Species: Rabbit
Developmental Toxicity: LOAEL: 1.000 mg/kg body weight
Result: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: LOAEL: 0,5 mg/kg body weight
Result: Malformations were observed., Cleft palate

Test Type: Embryo-fetal 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 fetal development.

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

Basic phenylmercury nitrate:

Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive
Remarks: Based on data from similar materials

Reproductive toxicity - As- : Clear evidence of adverse effects on development, based on

sessment animal experiments.

STOT-single exposure

Not classified based on available information.

Components:

Chloramphenicol:

Routes of exposure	:	Oral
Target Organs	:	Blood, Bone marrow

STOT-repeated exposure

Not classified based on available information.

Components:

Chloramphenicol:

Routes of exposure	:	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:

Routes of exposure	:	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 y
Remarks	:	Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Chloramphenicol:

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

prednisolone:

Ingestion	:	Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

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 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:

Basic phenylmercury nitrate:

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

Bioaccumulative potential

Components:

prednisolone:

Partition coefficient: n-octanol/water	:	log Pow: 1,46

Basic phenylmercury nitrate:

Partition coefficient: n-	:	log Pow: 1,27

octanol/water

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable
Control of precursors and essential chemicals for the preparation of drugs.	:	Not applicable

The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Revision Date	:	30.09.2023
Date format	:	dd.mm.yyyy

Further information

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

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AR OEL	:	Argentina. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
AR OEL / CMP	:	TLV (Threshold Limit Value)

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the

SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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