

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Prednisone (<10%) Formulation (Brazil)

Supplier's company name, address and phone number

Company name of supplier : MSD

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

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : 1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION**GHS classification of chemical product**

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Immune system, lymphatic system, Adrenal gland, Skin, Blood)

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Immune system, lymphatic system, Adrenal gland, Skin, Blood) through prolonged or repeated exposure if swallowed.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P280 Wear protective gloves/ protective clothing/ eye protec-

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

tion/ 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

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Starch	9005-25-8	>= 30 - < 40	8-98
Prednisone	53-03-2	>= 3 - < 10	9-743
Magnesium stearate	557-04-0	>= 0.4 - <= 1	2-611

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.

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue:
2.0	2025/04/14	11451117-00002	2024/10/18
			Date of first issue: 2024/10/18

Most important symptoms and effects, both acute and delayed	: Rinse mouth thoroughly with water. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Nitrogen oxides (NO _x) Metal oxides
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue:
2.0	2025/04/14	11451117-00002	2024/10/18
			Date of first issue: 2024/10/18

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.

7. HANDLING AND STORAGE**Handling**

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

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue:
2.0	2025/04/14	11451117-00002	2024/10/18
			Date of first issue: 2024/10/18

Storage

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Threshold limit value and permissible exposure limits for each component in the work environment**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m ³	ACGIH
Prednisone	53-03-2	TWA	30 µg/m ³	Internal
		Wipe limit	300 µg/100 cm ²	Internal
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	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 : Particulates type

Hand protection

Material : Chemical-resistant gloves

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

Eye protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: powder
Colour	: No data available
Odour	: odourless
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Boiling point, initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: Not applicable
Lower explosion limit and upper explosion limit / flammability limit	
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: Not applicable
Decomposition temperature	: No data available
pH	: No data available
Evaporation rate	: Not applicable
Auto-ignition temperature	: No data available
Viscosity	
Viscosity, kinematic	: Not applicable

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

Solubility(ies)	
Water solubility	: 312 mg/l
Solubility in other solvents	: slightly soluble Solvent: Methanol 5 g/lSolvent: Chloroform slightly soluble Solvent: Dioxane 6.7 g/lSolvent: Alcohol
Partition coefficient: n-octanol/water	: log Pow: 1.46
Vapour pressure	: Not applicable
Density and / or relative density	
Relative density	: No data available
Density	: No data available
Relative vapour density	: Not applicable
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available
Particle characteristics	
Particle size	: No data available

10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: May form explosive dust-air mixture 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.

11. TOXICOLOGICAL INFORMATION

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

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

Acute toxicity

Not classified based on available information.

Components:**Starch:**

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg

Prednisone:

Acute oral toxicity	: LD50 (Mouse): 1,680 mg/kg Remarks: Based on data from similar materials
Acute toxicity (other routes of administration)	: LD50 (Mouse): 600 mg/kg Application Route: Intramuscular LD50 (Mouse): 135 mg/kg Application Route: Intraperitoneal LD50 (Mouse): 101 mg/kg Application Route: Subcutaneous

Magnesium stearate:

Acute oral toxicity	: LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 Assessment: The substance or mixture has no acute oral toxicity Remarks: Based on data from similar materials
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:**Magnesium stearate:**

Species	: Rabbit
Result	: No skin irritation
Remarks	: Based on data from similar materials

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Starch:**

Species	: Rabbit
Result	: No eye irritation

Magnesium stearate:

Species	: Rabbit
Result	: No eye irritation
Remarks	: Based on data from similar materials

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Starch:**

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

Magnesium stearate:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative
Remarks	: Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:**Starch:**

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

Prednisone:

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

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

	Remarks: Based on data from similar materials
	Test Type: In vitro mammalian cell gene mutation test
	Result: negative
	Remarks: Based on data from similar materials
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
	Species: Rat
	Application Route: Oral
	Result: negative
	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
	Species: Mouse
	Application Route: Oral
	Result: negative
Germ cell mutagenicity - Assessment	: Weight of evidence does not support classification as a germ cell mutagen.

Magnesium stearate:

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

Carcinogenicity

Not classified based on available information.

Components:**Prednisone:**

Species	: Rat
Application Route	: Oral
Exposure time	: 2 Years
LOAEL	: 0.368 mg/kg body weight
Result	: negative
Remarks	: Based on data from similar materials

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

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

NOAEL	:	9 mg/kg body weight
Result	:	negative
Remarks	:	Based on data from similar materials

Reproductive toxicity

Suspected of damaging the unborn child.

Components:**Prednisone:**

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Remarks: Based on data from similar materials Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: foetal mortality, Reduced foetal weight Remarks: Based on data from similar materials Test Type: Embryo-foetal development Species: Mouse Application Route: Oral Developmental Toxicity: LOAEL: 20 mg/kg body weight Remarks: Based on data from similar materials
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.

Magnesium stearate:

Effects on fertility	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

STOT - repeated exposure

May cause damage to organs (Immune system, lymphatic system, Adrenal gland, Skin, Blood) through prolonged or repeated exposure if swallowed.

Components:**Prednisone:**

Target Organs	: Immune system, lymphatic system, Adrenal gland, Skin, Blood
Assessment	: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Starch:**

Species	: Rat
NOAEL	: $\geq 2,000$ mg/kg
Application Route	: Skin contact
Exposure time	: 28 Days
Method	: OECD Test Guideline 410

Prednisone:

Species	: Rat
NOAEL	: 2 mg/kg
LOAEL	: 6 mg/kg
Application Route	: Oral
Exposure time	: > 151 d
Target Organs	: lymphatic system, Adrenal gland, Skin, Blood
Remarks	: Based on data from similar materials

Magnesium stearate:

Species	: Rat
NOAEL	: > 100 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days
Remarks	: Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Prednisone:**

Ingestion	: Target Organs: Adrenal gland Symptoms: Fever, muscle pain, hypertension, Hypoglycemia Target Organs: Immune system
-----------	--

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Magnesium stearate:**

Toxicity to fish	: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EL50 (Daphnia magna (Water flea)): > 1 mg/l Exposure time: 47 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials No toxicity at the limit of solubility NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	: EC10 (Pseudomonas putida): > 100 mg/l Exposure time: 16 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Persistence and degradability**Components:****Magnesium stearate:**

Biodegradability	: Result: Not biodegradable Remarks: Based on data from similar materials
------------------	--

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

Bioaccumulative potential**Components:****Prednisone:**

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

Magnesium stearate:

Partition coefficient: n-octanol/water : log Pow: > 4

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

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

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

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

ger aircraft)

IMDG-Code

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION**Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law**Harmful Substances Prohibited from Manufacture**

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

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

Not applicable

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

Not applicable

Substances Subject to be Notified Names

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

Chemical name	Concentration (%)	Remarks
Magnesium stearate	>=0.4 - <=1	-

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

Substances Subject to be Indicated Names

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

Chemical name	Remarks
Magnesium stearate	-

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

Not applicable

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

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

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

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

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

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

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

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

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

16. OTHER INFORMATION

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

Further information

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

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New

Prednisone (<10%) Formulation (Brazil)

Version	Revision Date:	SDS Number:	Date of last issue: 2024/10/18
2.0	2025/04/14	11451117-00002	Date of first issue: 2024/10/18

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.

JP / EN