

# SAFETY DATA SHEET



## Prednisone (<10%) Formulation (Brazil)

Version 2.0 Revision Date: 14.04.2025 SDS Number: 11451090-00002 Date of last issue: 18.10.2024  
Date of first issue: 18.10.2024

---

### SECTION 1. IDENTIFICATION

Product identifier : Prednisone (<10%) Formulation (Brazil)

#### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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 in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 2

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

#### GHS label elements in accordance with ABNT NBR 14725 Standard

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.

P260 Do not breathe dust.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

# SAFETY DATA SHEET



## Prednisone (<10%) Formulation (Brazil)

|                |                              |                               |   |
|----------------|------------------------------|-------------------------------|---|
| Version<br>2.0 | Revision Date:<br>14.04.2025 | SDS Number:<br>11451090-00002 | Date of last issue: 18.10.2024<br>Date of first issue: 18.10.2024 |
|----------------|------------------------------|-------------------------------|---|

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

### Storage:

P405 Store locked up.

### 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 explosive dust-air mixture during processing, handling or other means.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name      | CAS-No.   | Classification  | Concentration (% w/w) |
|--------------------|-----------|---|-----------------------|
| Starch             | 9005-25-8 |   | >= 30 - < 50          |
| Prednisone         | 53-03-2   | Repr., 2<br>STOT RE,<br>(Oral)(Immune system, lymphatic system, Adrenal gland, Skin, Blood) , 1 | >= 5 - < 10           |
| Magnesium stearate | 557-04-0  |   | >= 1 - < 5            |

## 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 : 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

# SAFETY DATA SHEET



## Prednisone (<10%) Formulation (Brazil)

Version 2.0 Revision Date: 14.04.2025 SDS Number: 11451090-00002 Date of last issue: 18.10.2024 Date of first issue: 18.10.2024

Notes to physician : when the potential for exposure exists (see section 8).  
Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : 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<sub>x</sub>)  
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 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

**Prednisone (<10%) Formulation (Brazil)**

---

|                |                              |                               |   |
|----------------|------------------------------|-------------------------------|---|
| Version<br>2.0 | Revision Date:<br>14.04.2025 | SDS Number:<br>11451090-00002 | Date of last issue: 18.10.2024<br>Date of first issue: 18.10.2024 |
|----------------|------------------------------|-------------------------------|---|

---

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.<br>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.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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.  |
| Conditions for safe storage | : Keep in properly labeled containers.<br>Store locked up.<br>Store in accordance with the particular national regulations.   |
| Materials to avoid          | : Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases  |

---

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

| Components | CAS-No. | Value type<br>(Form of<br>exposure) | Control parame-<br>ters / Permissible<br>concentration | Basis |
|------------|---------|-------------------------------------|--|-------|
|            |         |                                     |  |       |

# SAFETY DATA SHEET



## Prednisone (<10%) Formulation (Brazil)

Version 2.0 Revision Date: 14.04.2025 SDS Number: 11451090-00002 Date of last issue: 18.10.2024 Date of first issue: 18.10.2024

|                    |           |  |                            |          |
|--------------------|-----------|--|----------------------------|----------|
| Starch             | 9005-25-8 | TWA                                    | 10 mg/m <sup>3</sup>       | ACGIH    |
| Prednisone         | 53-03-2   | TWA                                    | 30 µg/m <sup>3</sup>       | Internal |
|                    |           | Wipe limit                             | 300 µg/100 cm <sup>2</sup> | Internal |
| Magnesium stearate | 557-04-0  | TWA<br>(Inhalable particulate matter)  | 10 mg/m <sup>3</sup>       | ACGIH    |
|                    |           | TWA<br>(Respirable particulate matter) | 3 mg/m <sup>3</sup>        | 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.

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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Color : No data available

Odor : odorless

# SAFETY DATA SHEET



## Prednisone (<10%) Formulation (Brazil)

Version 2.0      Revision Date: 14.04.2025      SDS Number: 11451090-00002      Date of last issue: 18.10.2024  
Date of first issue: 18.10.2024

---

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 explosive dust-air mixture 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 : 312 mg/l

Solubility in other solvents : slightly soluble  
Solvent: Methanol  
5 g/l Solvent: Chloroform  
slightly soluble  
Solvent: Dioxane  
6,7 g/l Solvent: Alcohol

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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

# SAFETY DATA SHEET



## Prednisone (<10%) Formulation (Brazil)

Version 2.0 Revision Date: 14.04.2025 SDS Number: 11451090-00002 Date of last issue: 18.10.2024 Date of first issue: 18.10.2024

|                          |   |  |
|--------------------------|---|--|
| 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  |

## SECTION 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>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 exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>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<br>Remarks: Based on data from similar materials   |
| Acute toxicity (other routes of administration) | : | LD50 (Mouse): 600 mg/kg<br>Application Route: Intramuscular<br><br>LD50 (Mouse): 135 mg/kg<br>Application Route: Intraperitoneal<br><br>LD50 (Mouse): 101 mg/kg<br>Application Route: Subcutaneous |

**Prednisone (<10%) Formulation (Brazil)**

Version 2.0      Revision Date: 14.04.2025      SDS Number: 11451090-00002      Date of last issue: 18.10.2024  
Date of first issue: 18.10.2024

---

||

**Magnesium stearate:**

|                       |   |  |
|-----------------------|---|--|
| Acute oral toxicity   | : | LD50 (Rat): > 2.000 mg/kg<br>Method: OECD Test Guideline 423<br>Assessment: The substance or mixture has no acute oral toxicity<br>Remarks: Based on data from similar materials |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2.000 mg/kg<br>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 |

**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 sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Starch:**

|                    |   |                   |
|--------------------|---|-------------------|
| Test Type          | : | Maximization Test |
| Routes of exposure | : | Skin contact      |
| Species            | : | Guinea pig        |
| Result             | : | negative          |

**Prednisone (<10%) Formulation (Brazil)**

Version 2.0 Revision Date: 14.04.2025 SDS Number: 11451090-00002 Date of last issue: 18.10.2024  
Date of first issue: 18.10.2024

**Magnesium stearate:**

|                    |   |                                      |
|--------------------|---|--------------------------------------|
| Test Type          | : | Maximization Test                    |
| Routes of exposure | : | 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)<br>Result: negative |
|-----------------------|---|--|

**Prednisone:**

|                                     |   |   |
|-------------------------------------|---|---|
| Genotoxicity in vitro               | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br>Remarks: Based on data from similar materials                         |
|                                     |   | Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br>Remarks: Based on data from similar materials                      |
| Genotoxicity in vivo                | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Rat<br>Application Route: Oral<br>Result: negative   |
|                                     |   | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Oral<br>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<br>Result: negative<br>Remarks: Based on data from similar materials                             |
|                       |   | Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: negative<br>Remarks: Based on data from similar materials |
|                       |   | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative   |

# SAFETY DATA SHEET



## Prednisone (<10%) Formulation (Brazil)

Version 2.0 Revision Date: 14.04.2025 SDS Number: 11451090-00002 Date of last issue: 18.10.2024  
Date of first issue: 18.10.2024

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                            |
| 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 fetal development | : | Test Type: Embryo-fetal development<br>Species: Rabbit<br>Application Route: Oral<br>Remarks: Based on data from similar materials  |
|                              |   | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 30 mg/kg body weight<br>Result: Fetal mortality., Reduced fetal weight.<br>Remarks: Based on data from similar materials |
|                              |   | Test Type: Embryo-fetal development<br>Species: Mouse<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 20 mg/kg body weight<br>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<br>Species: Rat<br>Application Route: Ingestion |
|----------------------|---|--|

**Prednisone (<10%) Formulation (Brazil)**

Version 2.0      Revision Date: 14.04.2025      SDS Number: 11451090-00002      Date of last issue: 18.10.2024  
Date of first issue: 18.10.2024

|                              |  |
|------------------------------|--|
|                              | Method: OECD Test Guideline 422<br>Result: negative<br>Remarks: Based on data from similar materials   |
| Effects on fetal development | : Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |

**STOT-single exposure**

Not classified based on available information.

**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 |

**Prednisone (<10%) Formulation (Brazil)**Version  
2.0Revision Date:  
14.04.2025SDS Number:  
11451090-00002Date of last issue: 18.10.2024  
Date of first issue: 18.10.2024**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

**SECTION 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

# SAFETY DATA SHEET



## Prednisone (<10%) Formulation (Brazil)

Version 2.0 Revision Date: 14.04.2025 SDS Number: 11451090-00002 Date of last issue: 18.10.2024  
Date of first issue: 18.10.2024

---

### Persistence and degradability

#### Components:

##### **Magnesium stearate:**

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

### 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

### 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.

### Domestic regulation

#### **ANTT**

Not regulated as a dangerous good

# SAFETY DATA SHEET



## Prednisone (<10%) Formulation (Brazil)

Version 2.0 Revision Date: 14.04.2025 SDS Number: 11451090-00002 Date of last issue: 18.10.2024  
Date of first issue: 18.10.2024

### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - : Not applicable (LINACH)

Brazil. List of chemicals controlled by the Federal Police : 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 : 14.04.2025  
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/>

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 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 Or-

# SAFETY DATA SHEET



## Prednisone (<10%) Formulation (Brazil)

Version  
2.0

Revision Date:  
14.04.2025

SDS Number:  
11451090-00002

Date of last issue: 18.10.2024  
Date of first issue: 18.10.2024

ganisation 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.

BR / Z8