# SAFETY DATA SHEET

Revision date 09-September-2022

| 1. Identification  |  |  |
|--|--|--|
| Product identifier   |  |  |
| Product Name   | PREDNISOLONE, ANHYDROUS, MICRONIZED, USP |  |
| Other means of identification  |  |  |
| Product Code(s)  | PR101                                    |  |
| Synonyms   | None                                     |  |
| Recommended use of the chemical and restrictions on use  |  |  |
| Recommended use  | No information available                 |  |
| Restrictions on use  | No information available                 |  |
| Details of the supplier of the safety data sheet   |  |  |
| Supplier Address<br>Spectrum Chemical Mfg. Corp.<br>14422 South San Pedro St.<br>Gardena, CA 90248<br>(310) 516-8000 |  |  |
| Emergency telephone number   |  |  |
| Emergency Telephone  | Chemtrec 1-800-424-9300                  |  |

# 2. Hazard(s) identification

# **Classification**

Reproductive toxicity

Category 2

Hazards not otherwise classified (HNOC) Not applicable

# Label elements

Warning

# Hazard statements

Suspected of damaging fertility or the unborn child



Revision Number 2



Physical state Solid

Odor No information available

# **Precautionary Statements - Prevention**

Obtain special instructions before use Do not handle until all safety precautions have been read and understood Wear protective gloves/protective clothing/eye protection/face protection Wash face, hands and any exposed skin thoroughly after handling

# **Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention

# **Precautionary Statements - Storage**

Store locked up.

# **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

# Other information

May be harmful if swallowed.

# 3. Composition/information on ingredients

# Substance

| Chemical name           | CAS No  | Weight-% | Trade secret |
|-------------------------|---------|----------|--------------|
| Prednisolone, Anhydrous | 50-24-8 | 100      | *            |

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

# 4. First-aid measures

# Description of first aid measures

| General advice  | Show this safety data sheet to the doctor in attendance.   |  |
|---|--|--|
| Inhalation  | Remove to fresh air.   |  |
| Eye contact   | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.<br>Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open<br>while rinsing. Do not rub affected area. Get medical attention if irritation develops and<br>persists. |  |
| Skin contact  | Wash skin with soap and water.   |  |
| Ingestion   | Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.  |  |
| Self-protection of the first aider                          | Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).  |  |
| Most important symptoms and effects, both acute and delayed |  |  |
| Symptoms  | May cause redness and tearing of the eyes. Burning sensation.  |  |

## Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

| 5. Fire-fighting measures                                |  |  |
|--|--|--|
| Suitable Extinguishing Media                             | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.                            |  |
| Large Fire   | CAUTION: Use of water spray when fighting fire may be inefficient.   |  |
| Unsuitable extinguishing media                           | Do not scatter spilled material with high pressure water streams.  |  |
| Specific hazards arising from the chemical               | No information available.  |  |
| Explosion data<br>Sensitivity to mechanical impact none. |  |  |
| Sensitivity to static discharge                          | none.  |  |
| Special protective equipment for<br>fire-fighters        | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. |  |
| 6. Accidental release measures                           |  |  |
| Personal precautions, protective ec                      | quipment and emergency procedures  |  |
| Personal precautions                                     | Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.  |  |
| Other information  | Refer to protective measures listed in Sections 7 and 8.   |  |
| Methods and material for containment and cleaning up     |  |  |
| Methods for containment                                  | Prevent further leakage or spillage if safe to do so.  |  |
| Methods for cleaning up                                  | Pick up and transfer to properly labeled containers.   |  |
|  |  |  |

# 7. Handling and storage

# Precautions for safe handling

Advice on safe handlingHandle in accordance with good industrial hygiene and safety practice. Avoid contact with<br/>skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove<br/>contaminated clothing and shoes.Conditions for safe storage, including any incompatibilitiesStorage ConditionsStorage ConditionsStore locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

# 8. Exposure controls/personal protection

# Control parameters

**Exposure Limits** 

The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

| ······································ |   |
|--|---|
| Engineering controls                   | Showers<br>Eyewash stations<br>Ventilation systems.   |
| Individual protection measures, such   | ch as personal protective equipment   |
| Eye/face protection                    | If splashes are likely to occur, wear safety glasses with side-shields.   |
| Hand protection                        | Wear suitable gloves.   |
|  |   |
| Skin and body protection               | Wear suitable protective clothing.  |
| Respiratory protection                 | No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.  |
| General hygiene considerations         | Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. |

# 9. Physical and chemical properties

Appropriate engineering controls

# Information on basic physical and chemical properties

| information on basic physical and t |                                |                  |
|-------------------------------------|--------------------------------|------------------|
| Physical state                      | Solid                          |                  |
| Appearance                          | Crystalline powder             |                  |
| Color                               | White to Off-White             |                  |
| Odor                                | No information available       |                  |
| Odor threshold                      | No information available       |                  |
|                                     |                                |                  |
| Property                            | Values                         | Remarks • Method |
| рН                                  | no data available              | None known       |
| Melting point / freezing point      | 235 - 240 °C / 455 - 464 °F    | None known       |
| Boiling point / boiling range       | no data available              | None known       |
| Flash point                         | no data available              | None known       |
| Evaporation rate                    | no data available              | None known       |
| Flammability (solid, gas)           | no data available              | None known       |
| Flammability Limit in Air           |                                | None known       |
| Upper flammability or explosive     | No data available              |                  |
| limits                              |                                |                  |
| Lower flammability or explosive     | No data available              |                  |
| limits                              |                                |                  |
| Vapor pressure                      | No data available              | None known       |
| Vapor density                       | no data available              | None known       |
| Relative density                    | 1.3                            | None known       |
| Water solubility                    | Very slightly soluble in water | None known       |
| Solubility(ies)                     | Slightly soluble in alcohol    | None known       |
| Partition coefficient               | No data available              | None known       |
| Autoignition temperature            | no data available              | None known       |
| Decomposition temperature           |                                | None known       |
| Kinematic viscosity                 | no data available              | None known       |
| Dynamic viscosity                   | No data available              | None known       |
| ,                                   |                                |                  |
| Other information                   |                                |                  |
| Explosive properties                | No information available       |                  |
| Oxidizing properties                | No information available       |                  |
| Softening point                     | No information available       |                  |
| Molecular weight                    | No information available       |                  |
| VOC Content (%)                     | No information available       |                  |
| Liquid Density                      | No information available       |                  |
| · •                                 |                                |                  |

# **Bulk density**

No information available

| 10. Stability and reactivity   |   |  |
|--|---|--|
| Reactivity   | No information available.                 |  |
| Chemical stability   | Stable under normal conditions.           |  |
| Possibility of hazardous reactions   | None under normal processing.             |  |
| Conditions to avoid  | None known based on information supplied. |  |
| Incompatible materials   | None known based on information supplied. |  |
| Hazardous decomposition products None known based on information supplied. |   |  |

# 11. Toxicological information

# Information on likely routes of exposure

| Product Information  | · ·  |  |
|--|--|--|
| Inhalation   | Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.   |  |
| Eye contact  | Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.                  |  |
| Skin contact   | Specific test data for the substance or mixture is not available. May cause irritation. Prolonged contact may cause redness and irritation.                                    |  |
| Ingestion  | Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed. |  |
| Symptoms related to the physical, chemical and toxicological characteristics |  |  |
| Symptoms   | May cause redness and tearing of the eyes.   |  |
| Acute toxicity   |  |  |

Numerical measures of toxicity

# Delayed and immediate effects as well as chronic effects from short and long-term exposure

| Skin corrosion/irritation<br>Serious eye damage/eye irritation<br>Respiratory or skin sensitization<br>Germ cell mutagenicity | May cause skin irritation.<br>Classification based on data available for ingredients. Causes serious eye irritation.<br>No information available.<br>No information available. |
|---|--|
| Reproductive toxicity   | Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.                 |
| STOT - single exposure<br>STOT - repeated exposure<br>Aspiration hazard   | No information available.<br>No information available.<br>No information available.  |
| Other adverse effects   | No information available.  |
| Interactive effects   | No information available.  |

# 12. Ecological information

| Ecotoxicity                                      | The environmental impact of this product has not been fully investigated. |
|--|---|
| Persistence and degradability<br>Bioaccumulation | No information available.<br>Inherently biodegradable.                    |
| Other adverse effects                            | No information available.   |

# 13. Disposal considerations

| Waste treatment methods                |   |
|--|---|
| Waste from residues/unused<br>products | Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. |
| Contaminated packaging                 | Do not reuse empty containers.  |

# 14. Transport information

| DOT        | not regulated |
|------------|---------------|
| TDG        | not regulated |
| <u>MEX</u> | not regulated |
| ICAO (air) | not regulated |
| IATA       | not regulated |
| IMDG       | not regulated |
| RID        | not regulated |
| ADR        | not regulated |
| ADN        | not regulated |

# 15. Regulatory information

# International Inventories

TSCA

Complies

| Complies  |
|---|
| Complies  |
| This product complies with ENCS:  |
| This product complies with China:   |
| Complies  |
| Complies  |
| All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS). |
|   |

Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

# US Federal Regulations

# SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

# SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

# CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

# **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

# US State Regulations

# California Proposition 65

This product does not contain any Proposition 65 chemicals.

### U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

### U.S. EPA Label Information

# EPA Pesticide Registration Number Not applicable

# 16. Other information

 NFPA

 Health hazards
 2

 Flammability
 0

 Instability
 0

 Physical and chemical properties

 HMIS

 Health hazards
 2 \*

 Flammability
 0

 Physical hazards
 0

 Personal protection
 X

 Chronic Hazard Star Legend
 \* = Chronic Health Hazard

Key or legend to abbreviations and acronyms used in the safety data sheetLegendSection 8: EXPOSURE CONTROLS/PERSONAL PROTECTIONTWATWA (time-weighted average)CeilingMaximum limit value

STEL (Short Term Exposure Limit)

Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization **Revision date** 09-September-2022

**Revision Note** 

No information available.

Disclaimer

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet