

1. Identification

Product identifier PredniSONE Oral Solution USP, 5mg/5mL

Other means of identification None.

Recommended use Indicated for inflammation, severe allergies, complications of chronic illnesses, and other medical problems.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company name West-Ward Pharmaceuticals Corporation

Address 1809 Wilson Road
Columbus, Ohio 43228

Telephone (614) 276-4000

Emergency phone number (614) 276-4000

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word Warning

Hazard statement This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials. Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F). Keep container tightly closed.

Disposal Incineration of waste at an approved USEPA incinerator is recommended.

Hazard(s) not otherwise classified (HNOC) None known.

3. Composition/information on ingredients

Substances

Chemical name	Common name and synonyms	CAS number	%
PredniSone		53-03-2	5mg/5mL

Composition comments Refer to Physician's Desk Reference for common components present at <1%

4. First-aid measures

Inhalation Get medical attention if symptoms occur.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed The following side effects have been reported with corticosteroids: Anaphylactoid or hypersensitivity reactions, cardiovascular, endocrine, and gastrointestinal systems reactions.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

Use water spray to cool unopened containers.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).

Methods and materials for containment and cleaning up

Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F). Keep container tightly closed. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Ventilation should be matched to conditions.

Individual protection measures, such as personal protective equipment

Eye/face protection

None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin protection

Hand protection

For consumer use, no unusual precautions are necessary.

Other

None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection

None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties**Appearance**

Physical state	Liquid.
Form	Liquid.
Color	Colorless, clear.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Slightly soluble

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Exposure to light.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information**Information on likely routes of exposure**

Inhalation Not expected to be hazardous in final pharmaceutical form.

Skin contact Not expected to be hazardous in final pharmaceutical form.

Eye contact Not expected to be hazardous in final pharmaceutical form. Contact with eyes may cause temporary irritation.

Ingestion Ingestion may cause irritation and stomach discomfort. Anaphylactoid or hypersensitivity reactions may occur.

Symptoms related to the physical, chemical and toxicological characteristics

The following side effects have been reported with corticosteroids: Anaphylactoid or hypersensitivity reactions, cardiovascular, endocrine, and gastrointestinal systems reactions.

Information on toxicological effects

Acute toxicity

May be harmful if swallowed in large quantities.

Skin corrosion/irritation

Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation

May cause temporary eye irritation.

Respiratory or skin sensitization

Respiratory sensitization

Not a respiratory sensitizer.

Skin sensitization

Anaphylactoid or hypersensitivity reactions may occur.

Germ cell mutagenicity

This product is not expected to be mutagenic.

Carcinogenicity

Long-term studies in animals have not been conducted to evaluate carcinogenic potential

IARC Monographs. Overall Evaluation of Carcinogenicity

PredniSone (CAS 53-03-2)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Drug is present in breast milk. A decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated exposure

Not classified.

Aspiration hazard

Not classified.

Further information

See package insert.

12. Ecological information

Ecotoxicity

The product is not classified as environmentally hazardous.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

Mobility in soil

Expected to be mobile in soil.

Other adverse effects

None.

13. Disposal considerations

Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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

Not applicable.

15. Regulatory information

US federal regulations

This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

OSHA GHS: GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

PredniSone (CAS 53-03-2)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	25-April-2015
Revision date	-
Version #	01
References	<p>1) PredniSone Oral Solution USP, 5mg/5 mL, Package Insert, West-Ward Pharmaceuticals Corporation Columbus, Ohio</p> <p>2) PDR – Physicians Desk Reference.</p> <p>3) Ariel Websight. Regulatory and ChemExpert Database.</p>

Disclaimer	<p>West-Ward Pharmaceuticals Corporation cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.</p>
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