

SAFETY DATA SHEETS

This SDS packet was issued with item:

078926669

N/A

IN CASE OF EMERGENCY
Emergency Phone: (614) 276-4000



Boehringer Ingelheim
Roxane Laboratories

Page 1 of 3

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Common/Trade Name: Prednisone Tablets USP 1, 2.5, 5, 10, 20, 50 mg. Tablets

Chemical Name: 17,21-DIHYDROXPREGNA-1,4-DIENE-3,11-20-TRIONE

Formula : $C_{21}H_{26}O_5$

Synonyms: None

Manufacturer's Name: Roxane Laboratories Inc.

Address: 1809 Wilson Road
Columbus, Ohio 43228

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition	CAS#	Mg/tab	Exposure Limit
Prednisone	53-03-2	1, 2.5, 5, 10, 20, 50	None established

REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1% of solution

3. HAZARDS IDENTIFICATION

Primary Route(s) of Entry	Ingestion
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. The signs of overexposure are elevated blood pressure, insomnia, and mood changes

4. FIRST AID MEASURES

Eye Exposure	Flush with running water for 15 minutes holding eyelids open. Obtain medical attention.
Skin Exposure	Wash contaminated area twice with soap and water. Obtain medical attention.
Ingestion	Vomiting may be induced if person is conscious. Obtain medical attention.
Inhalation	Remove to fresh air. Restore and/or support breathing as needed. Obtain Medical attention.

5. FIRE AND EXPLOSION HAZARDS					
Flammability	Lower: N/A		Upper: N/A		
Flash Point	Not Applicable				
Extinguishing Media	Use media suitable for fire in surrounding area				
Special Fire Fighting Procedures	Wear full protective clothing and self-contained breathing apparatus				
Unusual Fire/Explosion Hazards	Not Applicable				
6. ACCIDENTAL RELEASE INFORMATION					
Using appropriate protective equipment (see Section 8). Sweep/wipe up and containerize spill material in a compatible container. Treat products and contaminated materials as if they were hazardous waste. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.					
7. PRECAUTIONS FOR SAFE HANDLING AND USE					
Precautions	Ensure good ventilation/exhaustion at the workplace with raw material. When engineering controls are not sufficient to control exposure, wear NIOSH approved respiratory protection. No precautions for handling finished product.				
Storage	Store only in the original container. Store away from foodstuffs. Keep container tightly sealed.				
8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT					
Engineering Controls	None needed for finished product. Use adequate ventilation when working with raw materials.				
Personal Protection	Goggles, Lab coat, Gloves				
9. PHYSICAL / CHEMICAL CHARACTERISTICS					
Appearance	Solid tablet	Melting point	Not available	Solubility in water	slight (active)
Odor	Slight	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available		
pH	Not available	Density	Not available		
10. STABILITY AND REACTIVITY DATA					
Stability	Stable				
Incompatibility	None known				
Hazardous Decomposition	Oxides of Carbon				
Conditions to avoid	Excessive heat				
11. TOXICOLOGICAL INFORMATION					
Intramuscular (mouse): 600 mg/kg Subcutaneous LD50 (mouse) 10 mg/kg.					
12. ENVIRONMENTAL IMPACT INFORMATION					
No information is currently available on the environmental impact of this product.					
13. DISPOSAL INFORMATION					
Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.					

14. TRANSPORTATION INFORMATION	
Not regulated by the United States Department of Transportation (USDOT). Ship according to state and local regulations if applicable.	
15. REGULATORY INFORMATION	
For NDC Numbers see package insert	
16. OTHER DATA	
Note to Physician: See package insert	
Date March 31 st 1998 Prednisone Tablets	Revision Date: August 11 th 2004

The information provided is believed to be complete and accurate. If this product is combined with other materials, deteriorates or becomes contaminated, it may pose hazards not mentioned in this MSDS. It is the users' responsibility to use the information according to the application. Roxane Laboratories Inc. assumes no responsibility or liability resulting from the use of this information.

SAFETY DATA SHEET

1. Identification

Product identifier	PredniSONE Tablets USP, 1 mg, 2.5mg, 5mg, 10mg, 20mg, 50mg
Other means of identification	
Product code	1mg white tablet, debossed with product identification "54 092" on one side, and scored on the other., 2.5mg white compressed tablet, debossed with product identification "54 339" on one side, and scored on the other., 5mg white compressed tablet, debossed with product identification "54 512" on one side, and scored on the other., 10mg white compressed tablet, debossed with product identification "54 899" on one side, and scored on the other., 20mg white compressed tablet, debossed with product identification "54 760" on one side, and scored on the other., 50mg white compressed tablet, debossed with product identification "54 343" on one side, and scored on the other
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	Boehringer Ingelheim Roxane Inc.
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 20 – 25 °C (68 - 77°F).
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	1mg - 50mg

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 (CO ₂).
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	Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. 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 Solid.

Form Tablet.

Color White.

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. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

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. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.
Skin contact	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust or powder may irritate the skin.
Eye contact	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate the eyes.
Ingestion	Ingestion may cause irritation and malaise. 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 Dust may irritate the eyes.

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 Due to the physical form of the product it is not an aspiration hazard.

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 Product components are soluble in water and will slowly dissolve and disperse.

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)*
Canada	Domestic Substances List (DSL)	No
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	1) PredniSone Tablets USP, 1mg, 2.5mg, 5mg, 10mg, 20mg, 50mg, Package Insert, Roxane Laboratories, Inc., Columbus, Ohio 2) PDR – Physicians Desk Reference. 3) Ariel Webinsight. Regulatory and ChemExpert Database.

Disclaimer

Boehringer Ingelheim Roxane Inc. 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.