

SAFETY DATA SHEETS

This SDS packet was issued with item:

078909498

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078014449 078380153 078926671 078926673

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078909906 078909907 078909908

SAFETY DATA SHEET

Phenobarbital Sodium Injection, USP



Section 1. Identification

GHS product identifier	: Phenobarbital Sodium Injection, USP
Synonyms	: None.
Product code	: NDC 0641-0476-21, NDC 0641-0476-25, NDC 0641-0477-21, NDC 0641-0477-25
Chemical family	: Anticonvulsant. Sedative.
Product type	: Regulated prescription drug.
Container information	: 1 ml vials.

Identified uses

Pharmaceutical.

Supplier's details	: West-Ward Pharmaceutical Corp. 465 Industrial Way West Eatontown NJ 07724 USA
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Emergency telephone number (with hours of operation)	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7
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Section 2. Hazards identification

OSHA/HCS status	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Classification of the substance or mixture	: ACUTE TOXICITY (oral) - Category 4 SKIN SENSITIZATION - Category 1 CARCINOGENICITY - Category 2

GHS label elements

Hazard pictograms



Signal word	: Warning
Hazard statements	: Harmful if swallowed. May cause an allergic skin reaction. Suspected of causing cancer.

Precautionary statements

General	: Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.
Prevention	: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wear protective gloves. Avoid breathing vapor. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace.
Response	: IF exposed or concerned: Get medical attention. IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth. IF ON SKIN: Wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention.



Section 2. Hazards identification

- Storage** : Store locked up.
- Disposal** : Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Hazards not otherwise classified** : None known.

Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture
- Other means of identification** : None.
- CAS number/other identifiers**
- CAS number** : Not applicable.
- Product code** : NDC 0641-0476-21, NDC 0641-0476-25, NDC 0641-0477-21, NDC 0641-0477-25

Ingredient name	%	CAS number
Propane-1,2-diol	60 - 100	57-55-6
Phenobarbital Sodium	5 - 10	57-30-7
Ethyl Alcohol	5 - 10	64-17-5
Water	5 - 10	7732-18-5
Benzyl Alcohol	1 - 5	100-51-6

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Section 4. First aid measures

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : May cause an allergic skin reaction.
- Ingestion** : Harmful if swallowed.

Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Adverse symptoms may include the following:
 - irritation
 - redness
- Ingestion** : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

- Specific hazards arising from the chemical** : No specific fire or explosion hazard.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
 - carbon dioxide
 - carbon monoxide
 - nitrogen oxides
 - metal oxide/oxides

- Special protective actions for fire-fighters** : No special measures are required.

- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Spill** : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Avoid exposure - obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Ethyl Alcohol	ACGIH TLV (United States, 3/2012). STEL: 1000 ppm 15 minutes. NIOSH REL (United States, 1/2013). TWA: 1900 mg/m ³ 10 hours. TWA: 1000 ppm 10 hours. OSHA PEL (United States, 6/2010). TWA: 1900 mg/m ³ 8 hours. TWA: 1000 ppm 8 hours. AIHA WEEL (United States, 10/2011). TWA: 10 ppm 8 hours.
Benzyl Alcohol	

Appropriate engineering controls

- : If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Environmental exposure controls

- : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures

- : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

- : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection

- : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

- : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

- : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

- : Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Appearance

Physical state	: Liquid.
Color	: Colorless.
Odor	: Not available.
Odor threshold	: Not available.
pH	: 9.2 to 10.2
Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Not available.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Soluble in the following materials: cold water and hot water.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials, acids and alkalis.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Phenobarbital Sodium	LD50 Oral	Rat	150 mg/kg	-
Ethyl Alcohol	LC50 Inhalation Vapor	Rat	124700 mg/m ³	4 hours
	LD50 Oral	Rat	7 g/kg	-
Benzyl Alcohol	LD50 Dermal	Rabbit	2000 mg/kg	-
	LD50 Oral	Rat	1230 mg/kg	-

Section 11. Toxicological information

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Ethyl Alcohol	Eyes - Moderate irritant	Rabbit	-	100 µL	-
	Skin - Moderate irritant	Rabbit	-	24 hours 20 mg	-
	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Moderate irritant	Rabbit	-	0.066666667 minutes 100 mg	-
Benzyl Alcohol	Eyes - Severe irritant	Rabbit	-	500 mg	-
	Skin - Mild irritant	Rabbit	-	400 mg	-
	Skin - Moderate irritant	Rabbit	-	24 hours 100 mg	-
	Skin - Mild irritant	Man	-	48 hours 16 mg	-
	Skin - Moderate irritant	Pig	-	100%	-

Sensitization

There is no data available.

Carcinogenicity

There is no data available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Ethyl Alcohol	Category 3	Not applicable.	Narcotic effects

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Ingestion.

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : May cause an allergic skin reaction.
- Ingestion** : Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

Long term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

Section 11. Toxicological information

Potential chronic health effects

General	: Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
Carcinogenicity	: Suspected of causing cancer. Risk of cancer depends on duration and level of exposure.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	1501.3 mg/kg
Inhalation (vapors)	555.6 mg/L

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Ethyl Alcohol	Acute EC50 17.921 mg/L Marine water Acute EC50 2000 µg/l Fresh water Acute LC50 25500 µg/l Marine water	Algae - Ulva pertusa Daphnia - Daphnia magna Crustaceans - Artemia franchiscana - Larvae	96 hours 48 hours 48 hours
Benzyl Alcohol	Acute LC50 42000 µg/l Fresh water Chronic NOEC 4.995 mg/L Marine water Chronic NOEC 0.375 µl/L Fresh water Acute EC50 640 mg/L Acute IC50 700 mg/L Acute LC50 10000 µg/l Fresh water	Fish - Oncorhynchus mykiss Algae - Ulva pertusa Fish - Gambusia holbrooki - Larvae Algae - Scenedesmus subspicatus Algae Fish - Lepomis macrochirus	4 days 96 hours 12 weeks 96 hours 72 hours 96 hours

Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
Benzyl Alcohol	OECD 301C 301C Ready Biodegradability - Modified MITI Test (I)	92 to 96 % - 28 days	-	-

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Benzyl Alcohol	-	-	Readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Ethyl Alcohol	-0.32	-	low
Benzyl Alcohol	0.87	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc})	: Not available.
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Other adverse effects	: No known significant effects or critical hazards.
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Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

Section 15. Regulatory information

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Phenobarbital Sodium	5 - 10	No.	No.	No.	Yes.	Yes.
Ethyl Alcohol	5 - 10	Yes.	No.	No.	Yes.	No.
Benzyl Alcohol	1 - 5	No.	No.	No.	Yes.	No.

State regulations

Massachusetts : The following components are listed: Ethyl Alcohol; Benzyl Alcohol
New York : None of the components are listed.
New Jersey : The following components are listed: Propane-1,2-diol; Ethyl Alcohol
Pennsylvania : The following components are listed: Propane-1,2-diol; Ethyl Alcohol; Benzyl Alcohol
California Prop. 65

No products were found.

International regulations

International lists : **Australia inventory (AICS)**: All components are listed or exempted.
China inventory (IECSC): Not determined.
Japan inventory: Not determined.
Korea inventory: Not determined.
Malaysia Inventory (EHS Register): Not determined.
New Zealand Inventory of Chemicals (NZIoC): Not determined.
Philippines inventory (PICCS): Not determined.
Taiwan inventory (CSNN): Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

Section 16. Other information

History

Date of issue mm/dd/yyyy : 12/15/2013

Version : 1

Revised Section(s) : Not applicable.

Prepared by : KMK Regulatory Services Inc.

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
UN = United Nations

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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%
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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	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.

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