



SAFETY DATA SHEET

Revision Date 13-Jul-2016

Version 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Pred Forte

Other means of identification

Product Code FP61

Synonyms Prednisolone Acetate

Recommended use of the chemical and restrictions on use

Recommended Use Corticosteroid

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet

Manufacturer

ALLERGAN
400 Interpace Parkway, Morris Corporate Center III
Parsippany, NJ 07054, USA
+1-800-272-5525

E-mail address SDS@Actavis.com

Emergency telephone number

Emergency Telephone

Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity	Category 2
Effects on or via lactation	Yes

Label elements

Emergency Overview

Danger

Hazard statements

H362 - May cause harm to breast-fed children
H361 - Suspected of damaging fertility or the unborn child



(Bad file name)

Appearance Liquid **Physical state** Liquid **Odor** No information available

Chemical Name
Prednisolone acetate

Symptoms

Adverse reactions have occurred with corticosteroid/antibacterial combination drugs which can be attributed to the corticosteroid component, the antibacterial component, or the combination. Exact incidence figures are not available since no denominator of treated patients is available. Reactions occurring most often from the presence of the antibacterial ingredient are allergic sensitizations. Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Sulfacetamide sodium may cause local irritation. The reactions due to the corticosteroid component in decreasing order of frequency are: elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, and delayed wound healing. Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticism after use of topical corticosteroids. Corticosteroid-containing preparations can also cause acute anterior uveitis or perforation of the globe. Mydriasis, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids. Secondary Infection The development of secondary infection has occurred after use of combinations containing corticosteroids and antibacterials. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of corticosteroid. The possibility of fungal invasion must be considered in any persistent corneal ulceration where corticosteroid treatment has been used. Secondary bacterial ocular infection following suppression of host responses also occurs.

Benzalkonium Chloride

Common adverse reactions of this medication are dry, burning, or stinging sensation in the eye. Exposure may include nausea, vomiting, cough, shortness of breath, headache.

Chemical Name
Prednisolone acetate

Medical Conditions Aggravated by Exposure

This ophthalmic ointment is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. This product is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation, to other sulfonamides and to other corticosteroids. (Hypersensitivity to the antimicrobial component occurs at a higher rate than for other components.)

Polysorbate 80

Hypersensitivity to the material

Precautionary statements

- P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
- P321 - Specific treatment (see supplemental first aid instructions on this label)
- P332 + P313 - If skin irritation occurs: Get medical advice/attention
- P362 - Take off contaminated clothing and wash before reuse
- P337 + P313 - If eye irritation persists: Get medical advice/attention
- P202 - Do not handle until all safety precautions have been read and understood
- P405 - Store locked up
- P501 - Dispose of contents/ container to an approved waste disposal plant
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P201 - Obtain special instructions before use
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P263 - Avoid contact during pregnancy/while nursing
- P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

Other Information

Unknown Acute Toxicity 17.7% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
Boric Acid	10043-35-3	233-139-2	15 - 40*
SODIUM CITRATE DIHYDRATE	6132-04-3	N/A	7 - 13*
SODIUM CHLORIDE USP	7647-14-5	231-598-3	5 - 10*
HYPROMELLOSE PHTHALATEHP50	9050-31-1	N/A	1 - 5*
Sodium Bisulfite	7631-90-5	231-548-0	1 - 5*
Polysorbate 80	9005-65-6	N/A	1 - 5*
Prednisolone acetate	52-21-1	200-134-1	1 - 5*
EDETATE DISODIUM USP	6381-92-6	N/A	0.1 - 1*
Benzalkonium Chloride	63449-41-2	264-151-6	<0.1*

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

4. FIRST AID MEASURES

First aid measures

General advice	Immediate medical attention is required.
Eye contact	Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.
Skin Contact	Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Inhalation	Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
Ingestion	Do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person. Drink plenty of water.

Chemical Name
Prednisolone acetate

Note to physicians

NOT FOR INJECTION INTO THE EYE. Prolonged use of corticosteroids may result in ocular hypertension/glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Acute anterior uveitis may occur in susceptible individuals, primarily Blacks. Prolonged use of this medication ophthalmic ointment may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with the use of topical corticosteroids. In acute purulent conditions of the eye, corticosteroids may mask infection or enhance existing infection. If the product is used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients. Corticosteroids should be used with caution in the presence of glaucoma.

Intraocular pressure should be checked frequently. A significant percentage of staphylococcal isolates are completely resistant to sulfonamides. The use of steroids after cataract surgery may delay healing and increase the incidence of filtering blebs. The use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of corticosteroid medication in the treatment of herpes simplex requires great caution. Topical steroids are not effective in mustard gas keratitis and Sjögren's keratoconjunctivitis. Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia and other blood dyscrasias. Sensitization may recur when a sulfonamide is readministered, irrespective of the route of administration.

Benzalkonium Chloride

Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Fire may produce irritating, corrosive and/or toxic gases.

Explosion data

Sensitivity to Mechanical Impact

Not impact sensitive.

Sensitivity to Static Discharge

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Use personal protective equipment as required. Keep people away from and upwind of spill/leak.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.

Methods for containment

Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up

Cover liquid spill with sand, earth or other non-combustible absorbent material. Cover powder spill with plastic sheet or tarp to minimize spreading. Sweep up and shovel into suitable containers for disposal.

7. HANDLING AND STORAGE

Advice on safe handling

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

Storage Conditions

Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

Incompatible materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL
Boric Acid 10043-35-3	STEL: 6 mg/m ³ inhalable fraction TWA: 2 mg/m ³ inhalable fraction	N/A	N/A	N/A
Sodium Bisulfite 7631-90-5	TWA: 5 mg/m ³	(vacated) TWA: 5 mg/m ³	TWA: 5 mg/m ³	N/A
Prednisolone acetate 52-21-1	N/A	N/A	N/A	13

NIOSH IDLH *Immediately Dangerous to Life or Health*

Other Information Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid	Appearance	Liquid
Color	No information available	Odor	No information available
Odor threshold	No information available		

<u>Property</u>	<u>Values</u>
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available

Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Other Information

Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY

Reactivity

Not defined As Reactive substance

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

Aerosol formation.

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**Acute toxicity**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Boric Acid	= 2660 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 0.16 mg/L (Rat) 4 h
SODIUM CHLORIDE USP	= 3000 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 42 g/m ³ (Rat) 1 h
Sodium Bisulfite	= 1310 mg/kg (Rat)	N/A	N/A
Polysorbate 80	= 34500 µL/kg (Rat)	N/A	N/A
Prednisolone acetate	= 1680 mg/kg (mouse)	N/A	N/A
Benzalkonium Chloride	N/A	= 1420 mg/kg (Rat)	N/A

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

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Boric Acid	No information available.	Presumed to have carcinogenic potential for humans.	Probable Reproductive Toxicant.	It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the

				appropriate action should be taken to prevent exposure.
Polysorbate 80	No information available.	Not suspected of being a human carcinogen.	This product does not contain any known or suspected reproductive hazards.	It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.
Prednisolone acetate	No information available.	Not suspected of being a human carcinogen.	Prednisolone has been shown to be teratogenic in mice when given in doses 1-10 times the human dose.	It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Systemically administered sulfonamides are capable of producing kernicterus in infants of lactating women. Because of the potential for serious adverse reactions in nursing infants from sulfacetamide sodium and prednisolone acetate ophthalmic ointments, a decision should be made whether to discontinue nursing or to discontinue the medication.
Benzalkonium Chloride	Not Suspected of being a Mutagen.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	No information available.	No information available

Target Organ Effects Eyes, Respiratory system, Skin.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 17.7% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral) 2045 mg/kg
ATEmix (dermal) 4271 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

Harmful to aquatic life with long lasting effects

52.81% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Boric Acid 10043-35-3	N/A	1020: 72 h Carassius auratus mg/L LC50 flow-through	115 - 153: 48 h Daphnia magna mg/L EC50
SODIUM CHLORIDE USP 7647-14-5	N/A	5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static

		Pimephales promelas mg/L LC50 static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 7050: 96 h Pimephales promelas mg/L LC50 semi-static	
Sodium Bisulfite 7631-90-5	N/A	240: 96 h Gambusia affinis mg/L LC50 static	119: 48 h Daphnia magna mg/L EC50

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Boric Acid 10043-35-3	N/A	N/A	N/A	-0.757
Prednisolone acetate 52-21-1	N/A	Low	N/A	N/A

Other adverse effects No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Do not reuse container. Dispose of contents/containers in accordance with local regulations.

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical Name	California Hazardous Waste Status
Boric Acid 10043-35-3	Toxic

14. TRANSPORT INFORMATION

- DOT** Not regulated
- TDG** Not regulated
- ICAO (air)** Not regulated
- IATA** Not regulated
- IMDG** Not regulated
- ADR** Not regulated
- ADN** Not regulated

15. REGULATORY INFORMATION

International Inventories

- TSCA** Not Listed
- DSL/NDSL** Not Listed
- EINECS/ELINCS** Not Listed

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

US Federal Regulations

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

Chemical Name	ACGIH	IARC	NTP	OSHA
Boric Acid 10043-35-3	-	-	-	X
Sodium Bisulfite 7631-90-5	-	Group 3	-	-

IARC (International Agency for Research on Cancer)

Not classifiable as a human carcinogen

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

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

Acute health hazard	No
Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium Bisulfite 7631-90-5	5000 lb	-	-	X

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Sodium Bisulfite 7631-90-5	5000 lb	-	RQ 5000 lb final RQ RQ 2270 kg final RQ

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Boric Acid 10043-35-3	X	-	-
Sodium Bisulfite 7631-90-5	X	X	X

16. OTHER INFORMATION

Revision Date

13-Jul-2016

Revision Note

No information available

Disclaimer

The information provided in this Material 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