SAFETY DATA SHEET

Revision Date 08-May-2019 **Version** 3

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

Product identifier
Product Name Blephamide ointment

Other means of identification
Product Code FG00205
Synonyms Prednisolone/Sulfacetamide sodium ophthalmic

Recommended use of the chemical and restrictions on use
Recommended Use Antibiotic Corticosteroid Steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

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 plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address SDS@Allergan.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 not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Emergency Overview

The product contains no substances which at their given concentration, are considered to be hazardous to health

Appearance Ointment **Physical state** Solid **Odor** No information available

Chemical Name	**Symptoms**
Sulfacetamide Sodium	Irritation, stinging and burning.
Prednisolone acetate	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 hypercorticoidism after use of topical corticosteroids. Corticosteroid-containing preparations can also cause acute anterior uveitis or perforation of the globe. Mydriaisis, 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.
Chemical Name	**Medical Conditions Aggravated by Exposure**
Sulfacetamide Sodium	This medication is contraindicated in individuals who have a hypersensitivity to sulfonamides or to any ingredient of the preparation.
Prednisolone acetate	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.)

Other Information

Unknown Acute Toxicity 100% 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-%
White Petrolatum	8009-03-8	232-373-2	30 - 60*
Mineral Oil	8012-95-1	232-384-2	15 - 40*
Sulfacetamide Sodium	127-56-0	204-848-4	7 - 13*
Vilvanolin	RM101099	N/A	1 - 5*
Prednisolone acetate	52-21-1	200-134-1	0.1 - 1*
Phenylmercuric Acetate	62-38-4	200-532-5	<0.1*

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

4. FIRST AID MEASURES

First aid measures

Eye contact Rinse immediately with plenty of water and seek medical advice.

Skin Contact Wash off immediately with soap and plenty of water while removing all contaminated

clothes and shoes.

Inhalation Remove to fresh air.

Ingestion Consult a physician if necessary.

Chemical Name	**Note to physicians**
Sulfacetamide Sodium	FOR TOPICAL EYE USE ONLY - NOT FOR INJECTION. 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. Sensitizations may recur when a sulfonamide is readministered, irrespective of the route of administration. Sensitivity reactions have been reported in individuals with no prior history of sulfonamide hypersensitivity. At the first sign of hypersensitivity, skin rash or other serious reaction, discontinue use of this preparation.
Prednisolone acetate	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.

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 protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions See Section 12 for additional ecological information.

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m³)
Mineral Oil 8012-95-1	TWA: 5 mg/m³ inhalable particulate matter excluding metal working fluids, highly & severely refined TWA: 5 mg/m³ inhalable particulate matter excluding metal working fluids	TWA: 5 mg/m³ (vacated) TWA: 5 mg/m³	IDLH: 2500 mg/m³ TWA: 5 mg/m³ STEL: 10 mg/m³	N/A
Prednisolone acetate 52-21-1	N/A	N/A	N/A	13
Phenylmercuric Acetate 62-38-4	TWA: 0.1 mg/m³ Hg S*	(vacated) Ceiling: 0.1 mg/m³ Hg	IDLH: 10 mg/m³ Hg Ceiling: 0.1 mg/m³ Hg TWA: 0.05 mg/m³ except Organo alkyls Hg vapor	N/A

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	Solid	**Appearance**	Ointment
Color	No information available	**Odor**	No information available
Odor threshold	No information available		

Property	**Values**
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
White Petrolatum	N/A	= 3600 mg/kg (Rabbit)	N/A
Mineral Oil	> 24 g/kg (Rat)	N/A	= 2062 ppm (Rat) 4 h
Sulfacetamide Sodium	16,500 mg/kg (mouse)	N/A	N/A
Prednisolone acetate	= 1680 mg/kg (mouse)	N/A	N/A
Phenylmercuric Acetate	= 22 mg/kg (Rat) = 41 mg/kg (Rat)	N/A	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
Sulfacetamide Sodium	No information available.	No studies have been conducted in animals or in humans to evaluate the possibility of these effects with ocularly administered sulfacetamide. Rats appear to be especially susceptible to the goitrogenic effects of sulfonamides, and long-term oral administration of sulfonamides has resulted in thyroid malignancies in these animals.	Pregnancy Category C. Animal reproduction studies have not been conducted with sulfonamide ophthalmic preparations. Kernicterus may occur in the newborn as a result of treatment of a pregnant woman at term with orally administered sulfonamides. There are no adequate and well controlled studies of sulfonamide ophthalmic preparations in pregnant women and it is not known whether topically applied sulfonamides can cause fetal harm when administered to a pregnant woman. This product should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.	Systemically administered sulfonamides are capable of producing kernicterus in infants of lactating women. Because of the potential for the development of kernicterus in neonates, a decision should be made whether to discontinue nursing or discontinue the drug taking into account the importance of the drug to the mother.
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 administrated 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.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 100% of the mixture consists of ingredient(s) of unknown toxicity

12. ECOLOGICAL INFORMATION

Ecotoxicity

100% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
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.

Chemical Name	RCRA	RCRA - Basis for Listing	RCRA - D Series Wastes	RCRA - U Series Wastes
Phenylmercuric Acetate 62-38-4	P092	-	-	-

Chemical Name	RCRA - Halogenated Organic Compounds	RCRA - P Series Wastes	RCRA - F Series Wastes	RCRA - K Series Wastes
Phenylmercuric Acetate 62-38-4	-	P092	-	-

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

Chemical Name	ACGIH	IARC	NTP	OSHA
Mineral Oil 8012-95-1	A2	Group 1 Group 3	Known	X
Phenylmercuric Acetate 62-38-4	-	Group 3	-	-

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	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

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

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Phenylmercuric Acetate 62-38-4	-	X	-	-

CERCLA

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

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Phenylmercuric Acetate 62-38-4	100 lb	100 lb	RQ 100 lb final RQ RQ 45.4 kg final RQ

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals

Chemical Name	California Proposition 65
Phenylmercuric Acetate - 62-38-4	Developmental

U.S. State Right-to-Know Regulations

16. OTHER INFORMATION

Revision Date	08-May-2019
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