

# SAFETY DATA SHEET

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Revision Number 1



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

### Product identifier

PHYSICIANS CARE EYEWASH

### Other means of identification

Synonyms None

### Recommended use of the chemical and restrictions on use

Recommended Use Medicinal products  
Uses advised against No information available

### Details of the supplier of the safety data sheet

Supplier Name NIAGARA PHARMACEUTICALS INC.  
Supplier Address 60 INNOVATION DRIVE  
FLAMBOROUGH  
ON  
L9H7P3  
CA  
Supplier Phone Number Phone:905-690-6277  
Fax:905-690-6281  
Supplier Email rjames@niagarapharmaceuticals.com

### Emergency telephone number

Company Emergency Phone Number 905-708-7962

## 2. HAZARDS IDENTIFICATION

### Classification

The Eyewash is an approved drug by the FDA used for cleansing the eye to help irritation or burning by removing loose foreign material. This drug product is considered exempt from SDS as it does not fall under the definition of "Hazardous product" as per regulations - 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).



## PHYSICIANS CARE EYEWASH

GHS Label elements, including precautionary statements**Precautionary Statements - Prevention**

For single use only

**Precautionary Statements - Response**

If concerned: Get medical advice/attention

**Precautionary Statements - Storage**

Store as per product label between 20°C to 25°C(68°F to 77°F)

**Precautionary Statements - Disposal**

Dispose of contents/container in accordance with local regulations

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

0% of the mixture consists of ingredient(s) of unknown toxicity

Other information

No information available

Interactions with Other Chemicals

No information available.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS No	Weight-%	Trade Secret
Boric acid (H3BO3)	10043-35-3	1 - 5	*
Sodium borate	1330-43-4	0.1 - 1	*

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

**4. FIRST AID MEASURES**First aid measures**Eye contact**

This product is a first aid measure for cleansing the eye to help relieve irritation or burning by removing loose foreign material.

**Skin contact**

None



## PHYSICIANS CARE EYEWASH

Inhalation	None
Ingestion	Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person.

**Most important symptoms and effects, both acute and delayed**

**Most Important Symptoms and Effects** No information available.

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician** Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

**Suitable Extinguishing Media**

None.

**Unsuitable extinguishing media**

No information available

**Specific hazards arising from the chemical**

None

**Hazardous Combustion Products**

None

**Explosion Data**

Sensitivity to Mechanical Impact No.

Sensitivity to Static Discharge No.

**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.





PHYSICIANS CARE EYEWASH

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

Personal precautions                      None

### Environmental precautions

Environmental precautions              Refer to protective measures listed in Sections 7 and 8.

### Methods and material for containment and cleaning up

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

Methods for cleaning up                  Soak up with inert absorbent material.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

Handling                                      Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

Storage                                        Store as sealed bottle. Do not use if seal is missing or broken. For single use only. Store as per product label between 20°C to 25°C(68°F to 77°F)

Incompatible Products                    None known based on information supplied.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

### Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Boric acid (H3BO3) 10043-35-3	TWA: 2 mg/m <sup>3</sup> inhalable fraction STEL: 6 mg/m <sup>3</sup> inhalable fraction	-	
Sodium borate 1330-43-4	STEL: 6 mg/m <sup>3</sup> inhalable fraction TWA: 2 mg/m <sup>3</sup> inhalable fraction	(vacated) TWA: 10 mg/m <sup>3</sup>	TWA: 1 mg/m <sup>3</sup>

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits Immediately Dangerous to Life or Health

Other Exposure Guidelines              Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d



## PHYSICIANS CARE EYEWASH

962 (11th Cir., 1992)

Appropriate engineering controls

Engineering Measures	Showers Eyewash stations Ventilation systems
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Individual protection measures, such as personal protective equipment

Eye/face protection	No special protective equipment required.
Skin and body protection	No special protective equipment required
Respiratory protection	No protective equipment is needed under normal use conditions.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state	Liquid		
Appearance	Clear, colorless. No visual impurities	Odor	Odorless
Color	No information available	Odor Threshold	No information available
<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	7.4	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Specific Gravity	1	None known	
Water Solubility	Completely soluble	None known	
Solubility in other solvents	No data available	None known	
Partition coefficient: n-octanol/water	No data available	None known	
Autoignition temperature	No data available	None known	
Decomposition temperature	No data available	None known	



## PHYSICIANS CARE EYEWASH

Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No data available	
Oxidizing properties	No data available	

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	

## 10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

None known based on information supplied.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None known

## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

## Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

## Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Boric acid (H3BO3) 10043-35-3	= 2660 mg/kg ( Rat )	> 2000 mg/kg ( Rabbit )	> 2.03 mg/L ( Rat ) 4 h



## PHYSICIANS CARE EYEWASH

Sodium borate 1330-43-4	= 2403 mg/kg ( Rat )	> 2000 mg/kg ( Rabbit )	-
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Information on toxicological effects

Symptoms No information available.

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

Sensitization No information available.

Mutagenic Effects No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Reproductive toxicity No information available

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Chronic Toxicity No known effect based on information supplied.

Target Organ Effects No information available

Aspiration Hazard No information available.

Numerical measures of toxicity Product Information

The following values are calculated based on chapter 3.1 of the GHS document  
Not applicable



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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Boric acid (H3BO3) 10043-35-3		72h LC50: = 1020 mg/L (Carassius auratus)		48h EC50: 115 - 153 mg/L
Sodium borate 1330-43-4	96h EC50: = 158 mg/L (Desmodesmus subspicatus) 96h EC50: 2.6 - 21.8 mg/L (Pseudokirchneriella subcapitata)	96h LC50: = 340 mg/L (Limanda limanda)		48h LC50: 1085 - 1402 mg/L

### Persistence and Degradability

No information available.

### Bioaccumulation

Chemical Name	Log Pow
Boric acid (H3BO3) 10043-35-3	-0.757

### Other adverse effects

No information available.

## 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

#### Disposal methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

#### Contaminated Packaging

Dispose of contents/containers in accordance with local regulations.

#### California Hazardous Waste Codes 561

This product contains one substance that is listed with the State of California as a hazardous waste. However the amounts used in this product is negligible and is of below the prescribed limits for toxicity.

Chemical Name	California Hazardous Waste
Boric acid (H3BO3) 10043-35-3	Toxic





PHYSICIANS CARE EYEWASH

## 14. TRANSPORT INFORMATION

<u>DOT</u>	NOT REGULATED
Proper Shipping Name	NON REGULATED
Hazard Class	N/A
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>ICAO</u>	Not regulated
<u>IATA</u>	Not regulated
Proper Shipping Name	NON REGULATED
Hazard Class	N/A
<u>IMDG/IMO</u>	Not regulated
Hazard Class	N/A
<u>RID</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated

## 15. REGULATORY INFORMATION

### International Inventories

TSCA	Complies
DSL	All components are listed either on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory  
 DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

### US Federal Regulations

#### 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



## PHYSICIANS CARE EYEWASH

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)

**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

**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	Rhode Island	Illinois
Sodium borate 1330-43-4		X	X		

**International Regulations**

Component	Carcinogen Status	Exposure Limits
Sodium borate 1330-43-4 ( 0.1 - 1 )		Mexico: TWA 1 mg/m <sup>3</sup>

**Canada****WHMIS Hazard Class**

Not applicable

**16. OTHER INFORMATION**

NFPA	Health Hazards 0	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazards 0	Flammability 0	Physical Hazard 0	Personal Protection X

**Prepared By**

Niagara Pharmaceuticals Inc.  
60 Innovation Drive  
Flamborough, ON, L9H7P3



PHYSICIANS CARE EYEWASH

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Revision Date	905-690-6277
Revision Note	12-Dec-2018
	No information available

**Disclaimer**

The information provided in this 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**







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## SAFETY DATA SHEET

### SECTION 1: PRODUCT IDENTIFICATION

**Product:** 10% Povidone Iodine (PVP-I) Solution Prep Pad

**Product Label Name:** Povidone Iodine Prep Pads

**CAS:** (PVP-I) 25655-41-8

**Relevant Product Use:** Topical Antiseptic

**Company Name and Address:** Dukal Corporation  
2 Fleetwood Court  
Ronkonkoma, NY 11779

**Emergency Telephone Number:** 631-656-3800

**Contact Outside USA:** +1-800-243-0741  
QA-RA-NY@dukal.com

**Revision Date:** 14-May-2018

### SECTION 2: HAZARDOUS IDENTIFICATION

**Hazard Class/Category:** Eye Irritation – 2A  
STOT SE – 3  
Skin Irritation – 2

**Hazard Symbol:**



**Signal Word:** Warning

**Hazard Statements:** Causes serious eye irritation. (H319)  
May cause respiratory irritation. (H335)  
Causes skin irritation. (H315)

**Precautionary statements:** Avoid breathing vapors. (P261)

**General:** Keep out of reach of children. (P102)

**Eyes:** IF IN EYES: Rinse cautiously with water for several minutes.  
If eye irritation persists: Get medical advice/attention.  
(P305+P338) (P337+P313)

**Respiratory:** IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON



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CENTER or doctor/physician if you feel unwell. (P304+P340)  
(P312)

**Skin:**

IF ON SKIN: Wash with plenty of soap and water.  
If skin irritation occurs: Get medical advice/ attention.  
(P303+P352) (P332 + P313)

### SECTION 3: INFORMATION ON INGREDIENTS

Component Name	CAS #	Concentration	EC #
Povidone Iodine	25655-41-8	10%	N/A (Pre-Registration: 918-309-2)

### SECTION 4: FIRST-AID MEASURES

**Emergency first aid procedures by route of exposure:**

**Inhalation:** Get medical aid immediately. Remove from exposure to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

**Ingestion:** If victim is conscious and alert, give 2-4 cups of milk or water. Never give anything by mouth to an unconscious person. Get medical aid immediately.

**Skin:** Get medical aid. Flush skin with plenty of soap and water for at least 15 minutes while removing contaminated clothing and shoes. Remove contaminated clothing and shoes.

**Eyes:** Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid immediately.

### SECTION 5: FIRE-FIGHTING MEASURES

**Flash Point:** 93.9°C

**Extinguishing Media:** Use methods appropriate for the surrounding fire.

**Products of Combustion:** During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

**Fire Fighting Equipment/Instructions:** Wear protective clothing and equipment suitable for the surrounding fire, including helmet, facemask, and self contained breathing apparatus.



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### SECTION 6: ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Provide ventilation. For large spills wear gloves, safety glasses, NIOSH approved respiratory protection if ventilation is not adequate.

**Environmental Precautions:** Prevent discharge to open waters.

**Methods for Clean-Up:** Clean up spills immediately, using the appropriate protective equipment. Avoid generating dusty conditions.

### SECTION 7: HANDLING AND STORAGE

**Handling:** Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Minimize dust generation and accumulation. Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion and inhalation.

**Storage:** Keep the container tightly closed and in a cool, well ventilated place.

### SECTION 8: EXPOSURE CONTROLS

**Povidone Iodine (25655-41-8)**

**Engineering Controls:** Normal room ventilation is usually adequate under normal use.

**Personal Protective Equipment (PPE):**

**Eye/Face Protection:** None needed under normal use. If exposed to unusual amount and splashing: Wear goggles, described by OSHA regulations in 29CFR 1910.133 or European Standard EN166.

**Skin Protection:** None needed under normal use -- Wear overalls or apron if splashing is possible.

**Respiratory Protection:** Follow the OSHA respirator regulations found in 29CFR 1910.134 or European Standard EN 149. Always use a NIOSH or European Standard EN 149 approved respirator when necessary.

**General Hygiene Considerations:** Wear appropriate protective clothing to prevent skin exposure.





## SAFETY DATA SHEET

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Non-woven saturated with 10% povidone iodine solution

**Appearance:** Yellowish-brown amorphous hygroscopic powder

**Odor:** Slight odor

**PH:** Not Available.

**Vapor Pressure:** 0.132mmHg at 25°C

**Flammability Properties** (see section 5)

**Solubility (in water):** Soluble

**Specific Gravity @ 25°C:** Not Available

**Evaporation Rate:** Not Available

**Auto-ignition temperature:** Not Available

**Melting Point:** 300°C

### SECTION 10: STABILITY AND REACTIVITY

**Stability:** Stable at normal ambient temperatures near 70°C (21°C)

**Condition to Avoid:** Not Available

**Incompatible Materials:** Ether, chloroform, acetone, ethylene oxide and carbon tetrachloride

**Hazardous Decomposition:** Not Available

**Hazardous Reactions:** Not Available

### SECTION 11: TOXICOLOGICAL INFORMATION

#### ACUTE EFFECTS:

##### A: General Product information

Povidone Iodine contains Iodine in a Povidone Carrier.

##### B: Acute Toxicity

Low order of acute toxicity is possible: The concentrations used clinically (0.1 to 20%) are toxic for granulocytes and monocytes. Povidone-iodine was cytotoxic to SH-SY5Y (neuronal) and RSC96 (Schwann) cells. Povidone-iodine preparation was ototoxic in guinea pigs.

Rat LD50 oral: >2000 mg/kg

Rat LD50 dermal: Estimated based on R21 classification: 400 < LD50 < 2000 mg/kg

Rat LC50 inhalation: Estimated based on R20 classification: 2 < LC50 < 10 mg/L/4h

#### CHRONIC EFFECTS: Component

**10% Povidone Iodine (25655-41-8)** -- This product is not expected to cause long term adverse effects

### SECTION 12: ECOLOGICAL INFORMATION

#### ENVIRONMENTAL MOBILITY

OSHA/GHS 16-Section Standard Format, Complies with EC 1907/2006,1272/2008



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This product is water soluble and is expected to remain primarily in water.

### ENVIRONMENTAL DEGRADABILITY

This product Oxides of nitrogen, irritating and toxic fumes and gases, iodine.  
This substance is expected to be removed in a waste water treatment facility.

### ECOTOXICITY AND BIOACCUMULATION

Low acute toxicity to aquatic organisms is expected.

## SECTION 13: DISPOSAL CONSIDERATIONS

### The following advice only applies to the product as supplied:

Combination with other material may well indicate another route or disposal. If in doubt, contact the local Authorities. Empty packaging should be taken for recycling, recovery or disposal through a suitably qualified or licensed contractor. Care should in any case be taken to ensure compliance with national and local regulations. This product is NOT suitable for disposal by either landfill or via municipal powers, drains, natural streams or rivers. This product should be disposed of in accordance with all applicable local and national regulations and to dispose of containers with care.

This material, as supplied, is not hazardous waste. This material could become a hazardous waste if it is mixed with or otherwise comes in contact with hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult appropriate national, regional, or local regulations for additional requirements.

Dispose of in accordance with local regulations.

## SECTION 14: TRANSPORTATION INFORMATION

**DOT** Material Not Regulated or Classified Hazardous

**UN-No.** Material Not Regulated or Classified Hazardous

**IATA** Material Not Regulated or Classified Hazardous

**IMDG/IMO** Material Not Regulated or Classified Hazardous

## SECTION 15: REGULATORY INFORMATION

### ECHA/REACH

Povidone-Iodine substance is in ECHA pre-registration status.

EC List No. 918-309-2: Envisage registration (consideration) status deadline is 31-May-2018.

### WHMIS / CANADA

Not Controlled.

**SECTION 16: OTHER INFORMATION**

**Issue Date:** 26-Mar-2014

**Revision Date:** 14-May-2018

**Hazard Class Calculation:** Classes calculated using:

- Globally Harmonized System of Classification and Labelling of Chemicals, Seventh Revised Edition. UN, 2017.
- Assessment Report: Iodine (including PVP-iodine), Product types 1, 3, 4, 22. Sweden, 13 December 2013.

After ECHA/REACH pre-registration deadline, status of PVP-iodine may change, requiring revision of this SDS and product hazard classifications.

**Disclaimer:**

The information provided in this SDS is correct and is to the best of our knowledge, at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.