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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 MEASURESFirst 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



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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.



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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 (H ₃ BO ₃) 10043-35-3	TWA: 2 mg/m ³ inhalable fraction STEL: 6 mg/m ³ inhalable fraction	-	
Sodium borate 1330-43-4	STEL: 6 mg/m ³ inhalable fraction TWA: 2 mg/m ³ inhalable fraction	(vacated) TWA: 10 mg/m ³	TWA: 1 mg/m ³

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



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962 (11th Cir., 1992)

Appropriate engineering controls

Engineering Measures	Showers
	Eyewash stations
	Ventilation systems

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	Odor	Odorless
Appearance	Clear, colorless. No visual impurities	Odor Threshold	No information available
Color	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	



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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 REACTIVITYReactivity

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 INFORMATIONInformation on likely routes of exposureProduct 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



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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 (H ₃ BO ₃) 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 (H ₃ BO ₃) 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 (H ₃ BO ₃) 10043-35-3	Toxic



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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



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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 RegulationsCalifornia 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 ³

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

Revision Date	905-690-6277 12-Dec-2018
Revision Note	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



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@dukul.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



SAFETY DATA SHEET

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.

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.

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

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:

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