



SAFETY DATA SHEET

Issue Date 03-Jun-2014

Revision Date 02-Jul-2014

Version 1

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

Product identifier

Product Name PRN Pharmacal Hexa-Caine

Other means of identification

Product Code PRN FP 30023604
NDC Number 49427-434-04

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	Company Name
Pegasus Laboratories, Inc. 8809 Ely Road Pensacola, FL 32514	Pegasus Laboratories, Inc. 8809 Ely Road Pensacola, FL 32514

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

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 Clear liquid **Physical state** Liquid **Odor** No information available

Hazards not otherwise classified (HNOC)

Other Information

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

Chemical Name	CAS No.	Weight-%
Propylene Glycol	57-55-6	35-45*

Lidocaine Hydrochloride	6108-05-0	2-4*
-------------------------	-----------	------

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

4. FIRST AID MEASURES

First aid measures

Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin Contact	Intended for application to skin.
Inhalation	Remove to fresh air.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Dry chemical. Water spray (fog). Foam. Carbon dioxide (CO₂).

Specific hazards arising from the chemical

No information available.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

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, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation, especially in confined areas.

Environmental precautions

Environmental precautions See Section 12 for additional ecological information.

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 Use personal protective equipment as required. Dam up. Cover liquid spill with sand, earth or other non-combustible absorbent material. Take up mechanically, placing in appropriate containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible materials Incompatible with oxidizing agents. Bleaching agent.

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

Appropriate engineering controls

Engineering Controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin and body protection No special technical protective measures are necessary.

Respiratory protection If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

General Hygiene Considerations Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid	Odor	No information available
Appearance	Clear liquid	Odor threshold	No information available
Color	Clear Light blue		
Property	Values	Remarks • Method	
pH	Not Available		
Melting point/freezing point	No information available		
Boiling point / boiling range	No information available		
Flash point	> 103 °C / > 218 °F		Pensky-Martens Closed Cup (PMCC)
Evaporation rate	> 1		
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	1.04		
Water solubility	Soluble in water		
Solubility in other solvents	No information available		
Partition coefficient	No information available		
Autoignition temperature	No information available		

Decomposition temperature No information available
Oxidizing properties No information available

Other Information

Density 9 lbs./gal.

10. STABILITY AND REACTIVITY

Reactivity

No data available

Chemical stability

Stable.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous polymerization

Will not occur.

Conditions to avoid

Extremes of temperature and direct sunlight.

Incompatible materials

Incompatible with oxidizing agents. Bleaching agent.

Hazardous Decomposition Products

May emit toxic fumes under fire conditions. Hydrocarbons. Carbon dioxide (CO₂). Carbon monoxide.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure**Product Information**

Inhalation May cause irritation of respiratory tract.

Eye contact Contact with eyes may cause irritation.

Skin Contact May cause irritation.

Ingestion May cause irritation.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Propylene Glycol 57-55-6	= 20000 mg/kg (Rat)	= 20800 mg/kg (Rabbit)	-

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.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 10% 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) 45917 mg/kg

ATEmix (dermal) 47754 mg/kg

12. ECOLOGICAL INFORMATION**Ecotoxicity**

10% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Propylene Glycol 57-55-6	19000: 96 h Pseudokirchneriella subcapitata mg/L EC50	51600: 96 h Oncorhynchus mykiss mg/L LC50 static 41 - 47: 96 h Oncorhynchus mykiss mL/L LC50 static 51400: 96 h Pimephales promelas mg/L LC50 static 710: 96 h Pimephales promelas mg/L LC50		10000: 24 h Daphnia magna mg/L EC50 1000: 48 h Daphnia magna mg/L EC50 Static

Persistence and degradability

No information available.

Bioaccumulation

No information available.

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, unless specified by the manufacturer.

14. TRANSPORT INFORMATION**DOT****Description**

The following guidelines apply for domestic ground transport. If shipping by air or ocean, please contact our Transportation Dept.

MEDICINES, NOI NMFC 58770, SUB 2

15. REGULATORY INFORMATION

This chemical is classified as a food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, and is therefore subject to labeling requirements under the Food and Drug Administration. These requirements differ from the classification criteria and hazard information required for safety data sheets and workplace labeling of chemicals.

U.S. EPA Label Information

EPA Pesticide Registration Number Not Applicable

International Inventories

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Not Listed
ENCS	Not Listed
IECSC	Not Listed
KECL	Not Listed
PICCS	Not Listed
AICS	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

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

Chemical Name	TSCA	DSL	NDSL	EINECS	ELINCS	ENCS	IECSC	KECL	PICCS	AICS
Propylene Glycol	X	X		X		X	X	X	X	X
Lidocaine Hydrochloride										X

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
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**U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Propylene Glycol 57-55-6	X		X

International Regulations

Mexico - Grade

Slight risk, Grade 1

16. OTHER INFORMATION

<u>NFPA</u>	Health hazards 0	Flammability 1	Instability 0	Physical and Chemical Properties -
<u>HMIS</u>	Health hazards 0	Flammability 1	Physical hazards 0	Personal protection X

Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of PBI Gordon Corporation's knowledge, information and belief at the date of this publication. The information given is designed only as 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 other process, unless specified in the text. PBI GORDON CORPORATION MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR COURSE OF PERFORMANCE OR USAGE OF TRADE. Given the variety of factors that can affect the use and application of this product, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the product to determine whether it is fit for a particular purpose and suitable for user's method of use or application. Each user is also responsible for evaluating the conditions of use and designing the appropriate protective mechanisms to prevent employee exposures, property damage, or release to the environment. PBI Gordon Corporation assumes no responsibility for injury to the recipient or third persons, or for any damage to any property resulting from misuse of the product.

End of Safety Data Sheet