

# SAFETY DATA SHEET

Issuing Date 17-June-1992

Revision Date 28-Jul-2015

Revision Number 3

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

### Product identifier

**Product Name** Americaine® Aerosol 037882

### Other means of identification

**Synonyms** None

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

**Recommended Use** OTC Pharmaceutical  
Consumer Goods

**Uses advised against** No information available

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

**Supplier Name** Insight Pharmaceuticals  
**Supplier Address** 660 White Plains Road  
Tarrytown, NY 10591  
USA  
**Supplier Phone Number** Contact Phone: 1-914- 524-6800  
**Supplier Email** PrestigeService@prestigebrands-custsvc.info  
**Emergency telephone number** Poison Control: 1-800-222-1222

**Company Emergency Phone Number** 1-800-344-7239

## 2. HAZARDS IDENTIFICATION

### Classification

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

### GHS Label elements, including precautionary statements

#### Emergency Overview

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

**Appearance** Clear Liquid

**Physical State at 20°C** Liquid

**Odor** Characteristic Odor

**Precautionary Statements - Prevention**

None

**Precautionary Statements - Response**

None

**Precautionary Statements - Storage**

None

**Precautionary Statements - Disposal**

None

**Hazards not otherwise classified (HNOC)**

Not applicable

**Unknown Toxicity**

None

**Other information**

None

**Interactions with Other Chemicals**

No information available

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS No	Weight-%	Trade Secret
Benzocaine	94-09-7	-	*
Polyethylene Glycol	25322-68-3	-	*
Isobutane (propellant)	75-28-5	-	*
Propane (propellant)	74-98-6	-	*

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

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

Avoid contact with eyes- if product gets into the eye, flush with water for 15 minutes

**Skin Contact**

In case of accidental contact, wash skin thoroughly with water. Remove contaminated clothing and continue to wash with water. If irritation develops or persists, contact a doctor.

**Inhalation**

Propellants are single asphyxiate. May cause dizziness, disorientation, headache, excitement, central nervous system depression, anesthesia. Benzocaine may cause irritation.

**Ingestion**

Ingestion – Induce vomiting immediately by giving two glasses of water and sticking finger down throat. Never give anything by mouth to an unconscious person. In all cases, call a physician.

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**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.

<b>5. FIRE-FIGHTING MEASURES</b>
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**Suitable Extinguishing Media**

Contain source. Self-contained breathing apparatus may be necessary. Use water fog or spray to cool exposed equipment and containers.

**Unsuitable extinguishing media**

Mixtures with air are highly flammable. Vapors are heavier than air and may travel to ignition sources. Explosion hazard due to propellant properties.

**Specific Hazards Arising from the Chemical**

Flammable. Keep product and empty container away from heat and sources of ignition.

**Hazardous Combustion Products**

Nitrogen oxides (NOx) Carbon oxides and other toxic gasses

**Explosion Data**

**Sensitivity to Mechanical Impact** No.

**Sensitivity to Static Discharge** May be ignited by friction, heat, sparks or flames.

**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**                      Avoid breathing vapors or mists

### Environmental Precautions

**Environmental Precautions**                      For large spills, contact Clean Harbors Environmental Services 610-539-6633. Prevent product from entering drains. Prevent spreading of vapors through sewers, ventilation systems and confined areas.

### Methods and material for containment and cleaning up

**Methods for Containment**                      Absorb spill with inert material (e.g. dry sand or earth), then place in a chemical waste container

**Methods for cleaning up**                      Take precautionary measures against static discharges. Take up with inert, damp, noncombustible material using clean non-sparking tools and place into loosely plastic containers for later disposal.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

**Handling**    Take precautionary measures against static discharges. Ensure adequate ventilation.

### Conditions for safe storage, including any incompatibilities

**Storage**    Store in well ventilated, cool, dry conditions, away from sources of high temperatures. 59 – 86 ° F (15-30 ° C)

**Incompatible Products**                      None known based on information supplied.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

### **Exposure Guidelines**

Chemical Name	ACGIH TLV	OSHA PEL
Propane 74-98-6	1000 ppm	Carcinogen- No
Isobutane 75-28-5	STEL: 800 ppm	Carcinogen- No

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 962(11th Cir., 1992) See section 15 for national exposure control parameters

### Appropriate engineering controls

**Engineering Measures** Ensure adequate ventilation, especially in confined areas

### Individual protection measures, such as personal protective equipment

**Eye/Face Protection** None needed for product. Material handlers should use safety glasses with side shields and rubber gloves if skin contact can occur.

**Skin and Body Protection** None needed for product. Material handlers should use safety glasses with side shields and rubber Gloves if skin contact can occur.

**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.

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Physical and Chemical Properties

<b>Physical State</b>	Liquid	<b>Odor</b>	Characteristic odor
<b>Appearance</b>	Clear to yellow oily liquid	<b>Odor Threshold</b>	No information available
<b>Color</b>	Clear/yellow		
<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks</u></b>	<b><u>Method</u></b>
<b>pH</b>	4-7	None known	
<b>Melting / freezing point</b>	No data available	None known	
<b>Boiling point / boiling range</b>	-44-31°F (propellant)	None known	
<b>Flash Point</b>	<-100 estimated for propellant	None known	
<b>Evaporation Rate</b>	> 1 (propellant) (Butyl Acetate = 1)	None known	
<b>Flammability (solid, gas)</b>	No data available	None known	
<b>Flammability Limit in Air</b>			
<b>Upper flammability limit</b>	8.5-9.5		
<b>Lower flammability limit</b>	1.9-2.1		
<b>Vapor pressure</b>	No data available	None known	
<b>Vapor density</b>	>1	None known	
<b>Specific Gravity</b>	1.117 to 1.137 (H <sub>2</sub> O=1)	None known	
<b>Water Solubility</b>	No data available	None known	
<b>Solubility in other solvents</b>	No data available	None known	
<b>Partition coefficient: n-octanol/water</b>	No data available	None known	
<b>Autoignition temperature</b>	No data available	None known	
<b>Decomposition temperature</b>	No data available	None known	
<b>Kinematic viscosity</b>	No data available	None known	
<b>Dynamic viscosity</b>	No data available	None known	
<b>Explosive properties</b>	No data available		
<b>Oxidizing Properties</b>	No data available		

**Other Information**

<b>Softening Point</b>	No data available
<b>VOC Content (%)</b>	No data available
<b>Particle Size</b>	No data available
<b>Particle Size Distribution</b>	

## 10. STABILITY AND REACTIVITY

**Reactivity**

No data available.

**Chemical stability**

Stable under recommended storage conditions.

**Possibility of Hazardous Reactions**

Risk of explosion if heated under confinement

**Hazardous Polymerization**

Hazardous polymerization does not occur.

**Conditions to avoid**

Keep away from open flames, hot surfaces and sources of ignition.

**Incompatible materials**

Oxygen and strong oxidizing materials

**Hazardous Decomposition Products**

Possible formation of carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

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

<b>Inhalation</b>	Propellants are single asphyxiate. May cause dizziness, disorientation, headache, excitement, central nervous system depression, anesthesia. Benzocaine may cause irritation.
<b>Eye/Skin Contact</b>	Immediately flush eye and skin with running water for at least 15 minutes. If irritation develops, contact physician.
<b>Ingestion</b>	Induce vomiting immediately by giving two glasses of water and sticking finger down throat. Never give anything by mouth to an unconscious person. In all cases, call a physician.

**Information on toxicological effects**

<b>Symptoms</b>	May cause contact dermatitis. Reported to be a mild sensitizer. Medical Conditions Generally Aggravated by Exposure: Known allergy or hypersensitivity to Benzocaine.
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**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Sensitization</b>	No information available.
<b>Mutagenic Effects</b>	No information available.
<b>Carcinogenicity</b>	Contains no ingredient listed as a carcinogen.
<b>Reproductive Toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Chronic Toxicity</b>	No known effect based on information supplied.
<b>Target Organ Effects</b>	No information available.
<b>Aspiration Hazard</b>	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

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

The environmental impact of this product has not been fully investigated

### Persistence and Degradability

No information available.

### Bioaccumulation

No information available.

### Other adverse effects

No information available.

## 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

#### **Disposal methods**

This material, as supplied, is a hazardous waste according to federal regulations (40 CFR 261) Dispose of in accordance with federal, state, and local regulations

#### **Contaminated Packaging**

Do not re-use empty containers. Offer for recycle where available.

## 14. TRANSPORT INFORMATION

### DOT

ORM-D

### TDG

**Proper shipping name** Drugs, Medicines, Toilet Preps  
**Hazard class** -

### MEX

Not regulated

### ICAO/IATA

### IMDG/IMO

**Proper shipping name** Aerosols,  
Flammable

**UN/ID No** 1950

**Hazard class** 2.1

**Packing Group** Page 9022 EMS2-13 (Isobutane)

ADR Not regulated

ADN Not regulated

## 15. REGULATORY INFORMATION

**This product is a drug and as such is regulated under the US Food and Drug Administration (FDA).**

### International Inventories

TSCA Exempt

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU 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

### 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

<b>Acute Health Hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire Hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	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

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International Regulations

**16. OTHER INFORMATION**

**HMIS**                      **Health Hazards** 1    **Flammability** 4    **Physical Hazard** 0

**Prepared By**                      Insight Pharmaceuticals Corporation  
660 White Plains Road  
Tarrytown, NY 10591  
1-914- 524-6800

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**Revision Note**                      Updated to GHS SDS format

**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**