Safety Data Sheet
Narcan (Naloxone Hydrochloride) Nasal Spray

SDS Revision Date: **09/17/2015**

1. Identification

1.1. Product identifier

Product Identity	Narcan (Naloxone Hydrochloride) Nasal Spray
Alternate Names	Chemical Formula C19H21NO4 • HCl

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use	See Technical Data Sheet.
Application Method	See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name	Adapt Pharma Inc., 100 Matsonford Road Building 4, Suite 201 Radnor, PA 19087
Customer Service: Adapt Pharma Inc.,	Tel: +1-844-232-7811 Email: info@adaptpharma.com

2. Hazard(s) identification

2.1. Classification of the substance or mixture

No applicable GHS categories.

2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

No applicable GHS categories.

[Prevention]:
No GHS prevention statements
[Response]:
No GHS response statements
[Storage]:
No GHS storage statements
[Disposal]:
No GHS disposal statements

3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Active Ingredient Name Naloxone Hydrochloride

Chemical Formula C19H21NO4 • HCl

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride, benzalkonium chloride, and sodium ethylenediaminetetraacetate. Hydrochloric acid may be used to adjust the pH.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Naloxone Hydrochloride **CAS Number: 0051481-60-8**	**1 - 5**	**Skin Irrit. 2;H315** **Eye Irrit. 2;H319** **STOT SE 3;H335**	**[1]**

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.
[1] Substance classified with a health or environmental hazard.
[2] Substance with a workplace exposure limit.
[3] PBT-substance or vPvB-substance.
*The full texts of the phrases are shown in Section 16.

4. First aid measures

4.1. Description of first aid measures

General In all cases of doubt, or when symptoms persist, seek medical attention.
Never give anything by mouth to an unconscious person.

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Eyes Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

Skin Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

4.2. Most important symptoms and effects, both acute and delayed

Overview Naloxone Hydrochloride is a solution containing naloxone hydrochloride, a competitive antagonist of opioid receptors. Clinically, Naloxone prevents or reverses the effects of opioids including respiratory depression, sedation and hypotension. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract, and a potent drug. Based on clinical use, possible target organs include the central nervous system and cardiovascular system.
Information on the absorption of this product via inhalation or skin contact is not available.
Avoid liquid aerosol generation and skin contact.

5. Fire-fighting measures

5.1. Extinguishing media

As with any fire, use extinguishing media appropriate for primary cause of fire

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx) and hydrogen chloride.

5.3. Advice for fire-fighters

None anticipated for this aqueous product.

ERG Guide No. ----

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up

Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water.

7. Handling and storage

7.1. Precautions for safe handling

No special handling required for hazard control under conditions of normal product use.

7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Incompatible materials: No data available.

7.3. Specific end use(s)

No data available.

8. Exposure controls and personal protection

8.1. Control parameters

Exposure

CAS No.	Ingredient	Source	Value
0051481-60-8	Naloxone Hydrochloride	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

Carcinogen Data

CAS No.	Ingredient	Source	Value
0051481-60-8	Naloxone Hydrochloride	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

8.2. Exposure controls

Respiratory Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Eyes Chemical safety glasses are recommended.

Skin Protective gloves (e.g. latex or nitrile) recommended.

Engineering Controls Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

Other Work Practices Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

9. Physical and chemical properties

Appearance	Clear colorless to slightly yellow aqueous Liquid
Odor	Odorless
Odor threshold	Not determined
pH	4.5
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	**Lower Explosive Limit:** Not Measured
	Upper Explosive Limit: Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	1.012/1.018
Solubility in Water	Not Measured
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured

9.2. Other information

No other relevant information.

10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx) and hydrogen chloride.

11. Toxicological information

Acute toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Naloxone Hydrochloride - (51481-60-8)	No data available	No data available	No data available	No data available	No data available

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

12. Ecological information

12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Naloxone Hydrochloride - (51481-60-8)	Not Available	Not Available	Not Available

12.2. Persistence and degradability

There is no data available on the preparation itself.

12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

13. Disposal considerations

13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	**DOT Hazard Class:** Not Applicable	**IMDG:** Not Applicable **Sub Class:** Not Applicable	**Air Class:** Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable

14.5. Environmental hazards

IMDG Marine Pollutant: No

14.6. Special precautions for user

No further information

15. Regulatory information

Regulatory Overview	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
Toxic Substance Control Act (TSCA)	All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification	Not Regulated
US EPA Tier II Hazards	**Fire:** No
	Sudden Release of Pressure: No
	Reactive: No
	Immediate (Acute): No

Delayed (Chronic): No

EPCRA 311/312 Chemicals and RQs:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 302 Extremely Hazardous:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Developmental Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

New Jersey RTK Substances (>1%) :
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Pennsylvania RTK Substances (>1%) :
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

End of Document

1. Product and Company Identification

PRODUCT NAME: AUVI-Q™ (epinephrine injection, USP)
0.3 mg or 0.15 mg Auto-Injector

Substance name: Epinephrine

Supplier:
Sanofi-aventis U.S. LLC
A SANOFI COMPANY
55 Corporate Drive
Bridgewater, NJ 08807

24-Hour Transport Emergency, US (Chemtrec):	**(800) 424-9300**
24-Hour Transport Emergency, outside US (Chemtrec):	**(703) 527-3887**
US Customer Service	**(800) 207-8049**
24-Hour Emergency, sanofi-aventis US:	**(908) 981-5550**

Product use: Pharmaceutical device.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification (epinephrine solution):
Acute toxicity - oral, Category 4
Acute toxicity - dermal, Category 4
Acute toxicity - inhalation, Category 4

2.2 Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, epinephrine:

Signal Word: Warning

Hazard Statement(s): Harmful if swallowed, if inhaled or in contact with skin.

Symbol(s): Exclamation mark

Precautionary Statement(s):

- Prevention: Avoid breathing spray. Use only in a well-ventilated area. Wear protective gloves. Wash hands thoroughly after handling. Do not eat, drink or smoke while using this product.

- Response: If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center if you feel unwell. If swallowed: Call a poison center if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water and soap. Take off contaminated clothing and wash it before reuse. Call a poison center if you feel unwell.

- Storage: Store locked up.

- Disposal: Dispose of contents and container in accordance with applicable regional, national and local laws and regulations.

2.3 Hazards Not Otherwise Classified (HNOC)

Not classified.

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3. Composition/Information on Ingredients

Chemical Name:	**Common Name:**	**CAS #:**	**Percentage or concentration range**
(-)-3,4-Dihydroxy-α-[(methylamino)methyl] benzyl alcohol	Epinephrine	51-43-4	0.11 %
Sulfurous acid, monosodium salt	Sodium bisulfite	7631-90-5	0.2 %
Sodium chloride	Sodium chloride	7647-14-5	1.2 %
Hydrochloric acid		7647-01-0	Trace (used for pH adjustment
Water	Water	7732-18-5	Balance (> 98%)

The device contains a small amount (about 1 mL) of inert gas (argon, CAS # 7440-37-1).

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4. First Aid Measures

4.1 First aid procedures

Eye contact: In case of contact with product, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention.

Skin contact: In case of contact with product, immediately flush skin with plenty of soap and water. Remove contaminated clothing and shoes. Call a poison center if you feel unwell.

Ingestion: If swallowed, call a poison center. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If product is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention. Call a poison center if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache and/or respiratory difficulties.

4.3 Indication of any immediate medical attention and special treatment needed

In case of accidental injection to the digits, hands, or feet, treatment should be directed at vasodilation. See package insert for additional information.

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5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

5.2 Specific hazards arising from the chemical

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

5.3 Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

6. Accidental Release Measures

6.1 Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn (see Section 8).

6.2 Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

6.3 Methods for containment:

Absorb spilled liquid with a suitable inert material, place in suitable container for disposal and mop area.

6.4 Methods for clean-up:

Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

7. Handling and Storage

7.1 Precautions for Safe Handling

Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Do not eat, smoke or drink while handling product. Wash hands thoroughly after handling.

7.2 Conditions for Safe Storage

Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light. Store at 20 – 25^{o}C (68 – 77^{o} F). Do not refrigerate.

Epinephrine solution deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure band, epinephrine: 1 - 10 micrograms/m^3, 8-hour TWA.

8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

8.3 Individual Protection Measures

Eye/face protection: Safety glasses or safety goggles should be worn if there is a potential for eye contact with the product.

Skin protection: Suitable protective gloves should be worn. Use of a protective or disposable gown or laboratory coat is recommended if there exists a potential for contact with the product.

Respiratory protection: None normally required for routine handling of the product. However, approved respiratory protection should be worn if there is a potential for exposure to the product. A respiratory protection program that meets OSHA 29 CFR 1910.134 and ANSI Z88.2 must be followed whenever workplace conditions warrant respirator usage.

General hygiene considerations: Wash hands before breaks and at the end of the work shift.

9. Physical and Chemical Properties

The following information is for the epinephrine product solution unless otherwise noted:

Appearance: Clear, colorless liquid.
Odor: No data available.
Odor threshold: No data available.
pH: 2.2 – 5.0
Freezing point: No data available.
Initial boiling point/boiling point range: No data available.
Flash point: No data available.
Evaporation rate: No data available.
Flammability: No data available.
Upper/lower flammability or explosive limits: No data available.
Vapor pressure: No data available.
Vapor density: No data available.

Relative density: 1.006 g/cm3 at 20 °C
Solubility: No data available.
Partition coefficient: n-octanol/water: No data available.
Auto-ignition temperature: No data available.
Decomposition temperature: No data available.
Viscosity: No data available.

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10. Stability and Reactivity

10.1 Reactivity

Not a reactive material under normal handling conditions.

10.2 Chemical Stability

Stable under normal handling conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to Avoid

Keep away from heat, sparks and flames.

10.5 Incompatible materials

Strong oxidizing and reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

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11. Toxicological Information

The following information is for the active ingredient epinephrine unless otherwise noted:

Information on likely routes of exposure: Not expected under normal handling conditions. Unintended spills or releases could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache and/or respiratory difficulties.

Effects of short-term (acute) exposure: Overexposure to epinephrine may cause serious and potentially fatal cardiovascular effects, including elevated arterial pressure, pulmonary edema, and transient bradycardia followed by tachycardia. See package insert.

Effects of long-term (chronic) exposure: No data available.

Acute toxicity (LD50):
Epinephrine:
Oral LD50, rat: 4 mg/kg
Dermal LD50, rat: 62 mg/kg.
Inhalation LD50, rat: 0.00125 mg/l

Sodium bisulfite:
Oral LD50, rat: 2,000 mg/kg.

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Sensitization: Sodium bisulfite: may cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons.

Epinephrine: No data available.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): No data available.

Carcinogenicity: Long-term studies to evaluate the carcinogenic potential of epinephrine have not been evaluated.

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Reproductive toxicity and teratogenicity: Epinephrine was teratogenic in rabbits, mice and hamsters. Epinephrine has been shown to have teratogenic effects when administered subcutaneously in rabbits at approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal dose of 1.2 mg/kg/day for two to three days), in mice at approximately 7 times the maximum daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal subcutaneous dose of 1 mg/kg/day for 10 days), and in hamsters at approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal subcutaneous dose of 0.5 mg/kg/day for 4 days).

These effects were not seen in mice at approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a subcutaneous maternal dose of 0.5 mg/kg/day for 10 days).

Mutagenicity: Epinephrine and other catecholamines have been shown to have mutagenic potential in vitro and to be an oxidative mutagen in a WP2 bacterial reverse mutation assay. Epinephrine was positive in the DNA Repair test with B. subtilis (REC) assay, but was not mutagenic in the Salmonella bacterial reverse mutation assay.

Aspiration hazard: No data available.

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12. Ecological Information

The following information is for the active ingredient epinephrine unless otherwise noted:

12.1. Ecotoxicity

Acute invertebrate toxicity: EC50 = 40.0 mg/L
Species: Daphnia magna
Duration of test: 24 hours

Acute invertebrate toxicity: EC50 = 31.7 mg/L
Species: Daphnia magna
Duration of test: 48 hours

12.2. Persistence and degradability

Biological degradability: approx. 41%; not readily biodegradable.
Duration of test: 28 days

12.3. Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Other adverse effects

No data available

13. Disposal Considerations

13.1 Disposal of product waste

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

Epinephrine (CAS # 51-43-4) is a RCRA listed hazardous waste, code P042.

The device contains two lithium button cell batteries and a small steel gas cell containing about 1 mL of argon.

California regulations: This product uses batteries containing perchlorate material.

13.2 Disposal of packaging waste

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

14. Transport Information

14.1 Basic shipping information, finished product

AUVI-Q™ contains two lithium metal batteries and should be shipped according to the current regulatory requirements applicable for lithium metal batteries contained in equipment and based on the mode of transport.

15. Regulatory Information

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.
Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.
SARA Title III:
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.
Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Not listed.
Massachusetts Right-To-Know List: Not listed.
New Jersey Right-To-Know List: Not listed.
Pennsylvania Right-To-Know List: Not listed.

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16. Other Information

Other Information: The information contained herein is based upon data considered true and accurate. Sanofi-aventis U.S. LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms

CAS: Chemical Abstracts Service
DOT: U.S. Department of Transportation
EST: Eastern standard time (U.S.)
IATA: International Air Transport Association
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
OEL: Occupational Exposure Limit
PPE: Personal Protection Equipment
SDS: Safety Data Sheet
STEL: Short-term exposure limit
TWA: Time-weighted average
U.S.: United States

Date Prepared: September 29, 2015

Second version.

MATERIAL SAFETY DATA SHEET

BAYER HEALTHCARE LLC
Consumer Care
36 Columbia Road
Morristown, NJ 07962-1910

TRANSPORTATION EMERGENCY
CALL CHEMTREC..... : (800) 424-9300
INTERNATIONAL ..... : (703) 527-3887

NON-TRANSPORTATION
BAYER EMERGENCY PHONE : (800) 331-4536
BAYER INFORMATION PHONE: (800) 331-4536
or (800) 743-5423

Section 1: Product and Company Identification

Product Name: Bayer Genuine Aspirin Children's Chewable, Orange Flavor
Material Number: 49711
Product Code: 105
Chemical Family: Analgesic

Section 2: Composition/Information on Ingredients

HAZARDOUS INGREDIENTS

Ingredient Name/ CAS Number	Exposure Limits	Concentration Min.	Max.

This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

Label Ingredients: Aspirin; Dextrose(Glucose); FD&C Yellow #6 Aluminum Lake; Flavoring; Sodium Saccharin; Pregelatinized Starch;

OTHER INGREDIENTS
The ingredients listed below are provided for informational purposes.

Ingredient Name/ CAS Number	Exposure Limits	Concentration Min.	Max.
Aspirin 50-78-2	**OSHA (PEL):** Not Established **ACGIH (TLV):** 5.00 mg/m3 TWA	30%	40%

Section 3: Hazards Identification

EMERGENCY OVERVIEW

CAUTION! Color: Orange **Form:** Tablets **Odor:** Citrus
Product poses little or no hazard if spilled and no unusual hazard if involved in a fire.

POTENTIAL HEALTH EFFECTS

Route(s) of Entry: Appropriate route of entry:, Ingestion

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

General Effects of Exposure

Acute Effects of Exposure: Exceeding the recommended dosage may cause: rapid or deep breathing, confusion, agitation, nausea, vomiting, diminished hearing, ringing in the ears or a loss of hearing occurs. hemorrhage, acid/base imbalances, coma, seizures, low blood pressure, irregular heartbeat, Allergic reactions are possible with symptoms of reddening, itching, rash, swelling of the face, throat or tongue, and breathing problems. dilation of pupils,

Chronic Effects of Exposure: Chronic overexposure to this product may cause effects as noted under acute overexposure. disturbances in liver function, disturbances in kidney function,

Carcinogenic Components:

NTP: None

IARC: None

OSHA: None

Medical Conditions Aggravated by Exposure: Asthma, Kidney disorders, if you are allergic to aspirin or any other pain reliever/fever reducer., Hypersensitivity to other pain relievers, Young children, the elderly, and pregnant women may be more susceptible to the effects of this product, Children and teenagers with chickenpox or flu symptoms, Persons who are at risk for hemorrhage, Taking prescription medications, Persons consuming alcohol may be more susceptible to the effects of this product

Human Health Effects Postnote: This is a pharmaceutical material available without a prescription. Use only as directed. See carton for full directions and warnings.

Section 4: First Aid Measures

First Aid for Eye: In case of contact, flush with copious amounts of water for at least 15 minutes. Call a physician.

First Aid for Skin: Not applicable.

First Aid for Inhalation: Not applicable.

First Aid for Ingestion: In case of overdose, contact your regional poison control center or physician immediately. Contact U.S. Poison Control Center at 1-800-222-1222.

Section 5: Fire Fighting Measures

Flash Point: Not Applicable

Flammable Limits:

Upper Explosion Limit (UEL %):

Lower Explosion Limit (LEL %): Not Established

Auto-ignition Temperature: Not Applicable

Extinguishing Media:

Suitable: All extinguishing media are suitable.

Special Fire Fighting Procedures: Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

Section 6: Accidental Release Measures

Spill or Leak Procedures: Spills should be swept up and placed in appropriate containers for disposal. Avoid creating dusty conditions.

Section 7: Handling and Storage

Storage Temperature: Room Temperature

Shelf Life: Do not use after expiration date.

Special Sensitivity: None known.

Handling/Storage Precautions: Keep this and all drugs out of the reach of children. Avoid contact with eyes. Avoid excessive contact with skin or clothing. Wash thoroughly after handling. Store in a dry place away from excessive heat. Reseal containers immediately after use. Use normal precautions for storage of a drug.

Section 8: Exposure Controls/Personal Protection

Personal Protection Equipment

Eye Protection Requirements: None for normal use.

Skin Protection Requirements:	No special skin protection requirements during normal handling and use.
Ventilation Requirements:	Under normal conditions of use, special ventilation is not required.
Respirator Requirements:	Under normal conditions of use, respiratory protection is not required.
Work Practices:	Normal clinical practice. Use good personal hygiene - wash hands and exposed skin thoroughly with soap and water after each use.
Additional Protective Measures:	Employers shall provide handwashing facilities which are readily accessible to employees. Educate and train employees in the safe use and handling of this product.

Section 9: Physical and Chemical Properties

Appearance:	Tablets
Color:	Orange
Odor:	Citrus
pH:	Not Applicable
Boiling Point:	Not Applicable
Melting/Freezing Point:	Not Established
Solubility in Water:	Soluble
Specific Gravity:	Not Applicable
Bulk Density:	Not Applicable
Vapor Pressure:	Not Applicable

Section 10: Stability and Reactivity

Stability:	Stable
Hazardous Polymerization:	Will not occur
Substances to Avoid:	See carton for full directions and warnings.
Conditions to Avoid:	Avoid extreme heat., Avoid contact with moisture / water.
Decomposition Products:	None known.

Section 11: Toxicological Information

Toxicity Data for Bayer Genuine Aspirin Children's Chewable, Orange Flavor

Toxicity Note: No data available for this product.

Toxicity Data for Aspirin

Acute oral toxicity: LD50 = > 1,100 mg/kg bw (Rat)

Section 12: Ecological Information

Ecological Data for Bayer Genuine Aspirin Children's Chewable, Orange Flavor
Ecological Note: No data available for this product.

Section 13: Disposal Considerations

Waste Disposal Method: Waste disposal should be in accordance with existing federal, state and local environmental control laws.

Section 14: Transportation Information

Technical shipping name: Nonprescription drug

Domestic Surface Transportation (DOT)
Hazard Class or Division: Non-Regulated

Marine Transportation (IMO / IMDG)
Hazard Class Division Number: Non-Regulated

Air Transportation (ICAO / IATA)
Hazard Class Division Number: Non-Regulated

Section 15: Regulatory Information

United States Federal Regulations

OSHA Hazcom Standard Rating: Not subject to OSHA

TSCA Inventory List: **This product is exempt from TSCA under Section 3 (2)(B)(vi) when used for pharmaceutical application.**

CERCLA Hazardous Substance:

Component(s)	Reportable Quantity
None	

SARA Title III
SARA Section 302 Extremely Hazardous Substances:

Component(s)/ CAS Number	Concentration Min.	Max.
Exempt		

SARA Section 311/312 Hazard Exempt from SARA Section 311/312

Categories:

SARA Section 313 Toxic Chemicals:

Component(s)/ CAS Number	Reporting Threshold	Concentration Min.	Max.
Exempt			

RCRA Status: If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

State Right-to-Know Information

Component(s)/ CAS Number	**State Code**	**Concentration Min.**	**Max.**

State Code Translation Table

Section 16: Other Information

HMIS Rating

Health		1
Flammability		0
Reactivity		0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe
*=Chronic Health Hazard

BAYER HEALTHCARE LLC's method of hazard communication is comprised of Product Labels and Material Safety Data Sheets. HMIS and NFPA ratings are provided by BAYER HEALTHCARE LLC as a customer service.

Contact: Phil Cornejo
Phone: 717-866-3855
MSDS Number: 000000001066
Version Date: 02/26/2010
MSDS Version: 1.11

Indicates Relevant Change Made.

MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name	**Glutose (Grape and Lemon Flavors)**
Version #	01
Issue date	12-18-2012
Revision date	-
Supersedes date	-
CAS #	Mixture
Product code	5006915, 5006930, 5006945, 5007015, 5007030
Product use	Oral glucose gel.
Manufacturer/Supplier	Perrigo Company 3940 Quebec Ave North Minneapolis, MN 55427 US
Telephone:	763-546-4676
Emergency	Emergency Telephone: (888) 464-2986 Global Incident Response No.: (760) 476-3962 Global Response Access Code: 333304

2. Hazards Identification

Physical state	Liquid.
Appearance	Clear colorless viscous gel with small bubbles throughout.
Emergency overview	CAUTION! May cause eye irritation. May cause skin irritation. May be harmful if swallowed in large quantities. For topical use only. Consumers: Refer to the package for consumer-specific information about the directional use and effects of this product. Only information about the ingredients that are expected to contribute to the potential health effects of the product are included. Prescription only medicine.
OSHA regulatory status	This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).
Potential health effects	
Routes of exposure	Ingestion. Eye contact. Skin contact.
Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	No inhalation hazard under normal conditions.
Ingestion	May be harmful if swallowed in large quantities. May cause abdominal pain, swelling and mild diarrhea.
Target organs	Eyes.
Chronic effects	Long-term usage may cause possible hypersensitization in susceptible individuals.
Potential environmental effects	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Dextrose Anhydrous	50-99-7	30-50
Glycerin	56-81-5	3-7
Lemon flavor	NA	1-5
Cellulose gum	NA	0.5-1.5

4. First Aid Measures

First aid procedures

Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops or persists.
Skin contact	Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing if required, then physically remove as much of the product as possible. Wash affected area with soap and water, then thoroughly flush the area with water. If irritation persists, seek medical advice.
Inhalation	If symptomatic, move to fresh air. Get medical attention, if needed.
Ingestion	If symptomatic, seek medical advice.

5. Fire Fighting Measures

Flammable properties	None known.
Extinguishing media	
Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	Not applicable.
Protection of firefighters	
Protective equipment and precautions for firefighters	Wear self-contained breathing apparatus and protective clothing.
Fire fighting equipment/instructions	Not available.
Hazardous combustion products	Carbon oxides. May produce toxic fumes if heated to decomposition.

6. Accidental Release Measures

Personal precautions	Wear appropriate personal protective equipment (See Section 8).
Methods for cleaning up	Recover by pumping or with suitable absorbent. Flush area clean with lots of water. Be aware of potential for surfaces to become slippery.

7. Handling and Storage

Handling	Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
Storage	Keep only in the original container. Store at controlled room temperature at 15–30 °C (59-86°F).

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Glycerin (CAS 56-81-5)	TWA	10 mg/m3	Mist.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Glycerin (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Glycerin (CAS 56-81-5)	TWA	10 mg/m3	Mist.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Glycerin (CAS 56-81-5)	TWA	3 mg/m3	Respirable mist.
		10 mg/m3	Mist.

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value	Form
Glycerin (CAS 56-81-5)	TWA	10 mg/m3	Mist.

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value	Form
Glycerin (CAS 56-81-5)	TWA	10 mg/m3	Mist.

Mexico. Occupational Exposure Limit Values

Components	Type	Value	Form
Glycerin (CAS 56-81-5)	TWA	10 mg/m3	Mist.

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 (typically 10 air changes per hour) 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 to an acceptable level.

Personal protective equipment

Eye / face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin protection None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

General hygiene considerations Wash hands after handling. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical & Chemical Properties

Appearance	Clear colorless viscous gel with small bubbles throughout.
Physical state	Liquid.
Form	Liquid Gel
Color	Colorless.
Odor	Slight lemon.
Odor threshold	Not available.
pH	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not available.
Solubility (water)	Soluble in water.
Specific gravity	Not available.
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.

Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Stable.
Conditions to avoid	Elevated temperatures.
Incompatible materials	None known.
Hazardous decomposition products	None known.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Sensitization	Not a skin or respiratory sensitizer.
Local effects	May cause eye irritation.
Chronic effects	Long-term usage may cause possible hypersensitization in susceptible individuals.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Mutagenicity	This product is not expected to cause mutagenic or genotoxic effects.
Reproductive effects	This product is not expected to cause reproductive or developmental effects.

12. Ecological Information

Ecotoxicity	This product's components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data available.
Bioaccumulation / Accumulation	No data available.
Partition coefficient	
Glycerin	-1.76
Mobility in environmental media	No negative effects on the aquatic environment are known.

13. Disposal Considerations

Disposal instructions	Dispose in accordance with applicable federal, state, and local regulations. No specific disposal method required.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Dispose of empty containers according to applicable federal, state/provincial and/or local regulations.

14. Transport Information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. One or more components are not listed on TSCA.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
Section 302 extremely hazardous substance (40 CFR 355, Appendix A)	No
Section 311/312 (40 CFR 370)	Yes
Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Not controlled
Canadian regulations	This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.
WHMIS status	Non-controlled

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US - New Jersey RTK - Substances: Listed substance

Glycerin (CAS 56-81-5) Listed.

US. Massachusetts RTK - Substance List

Glycerin (CAS 56-81-5) Listed.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Glycerin (CAS 56-81-5) Listed.

16. Other Information

Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1 Flammability: 1 Physical hazard: 0

NFPA ratings	Health: 1 Flammability: 1 Instability: 0
Disclaimer	This MSDS has been prepared for occupational exposure. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

Section 1. Identification

1.1 Substance Name: Nitroglycerin Sublingual Tablets

1.2 Relevant identified uses of the substance or mixture and uses advised against:
Pharmaceutical product for the treatment of angina pectoris

1.3 Company Identification: Glenmark Pharmaceuticals Inc., USA

750 Corporate Drive

Mahwah, NJ 07430

1.4 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Classification according to Regulation GHS
Acute Oral Toxicity: Category 4
Acute Toxicity - Dusts and Mists: Category 4
Specific target organ systemic toxicity (repeated exposure): Category 2

EU Classification:
EU Indication of danger: Toxic

2.2 Label elements

Signal Word: Warning

2.3 Risk Phrase:
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.
R33 - Danger of cumulative effects

Statement of Hazard:
H304 - May be fatal if swallowed and enters airways
H332 - Harmful if inhaled
H373 - May cause damage to organs through prolonged or repeated exposure: cardiovascular

2.4 Safety Advice:
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P271 - Use only outdoors or in a well-ventilated area
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P314 - Get medical attention/advice if you feel unwell
P501 - Dispose of contents/container in accordance with all local and national regulations

2.3 Other hazards:
Australian Hazard Classification (NOHSC):
Hazardous Substance: Non-Dangerous Goods.
Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3- Composition/Information on Ingredients

3.1 Substances

Sr No	Ingredients	CAS No.	0.3mg strength % composition	0.4mg strength % composition	0.6mg strength % composition
1	Diluted Nitroglycerin (2 %w/w Nitroglycerin in lactose)	55-63-0	0.75	1	1.5
2	Glyceryl Behenate	Not Known	Proprietary	Proprietary	Proprietary
3	Starch 1500 (Pregilatinized Starch)	9005-25-8	Proprietary	Proprietary	Proprietary
4	Lactose Monohydrate (Pharmatose 200M)	64044-51-5	Proprietary	Proprietary	Proprietary
5	Hydrophobic Colloidal Silica ((Aerosil@ R972 Pharma)	Not Known	Proprietary	Proprietary	Proprietary
6	Croscarmellose Sodium (Ac-Di-Sol SD-711)	Not Known	Proprietary	Proprietary	Proprietary
7	Calcium Stearate	1592-23-0	Proprietary	Proprietary	Proprietary

Section 4. First aid Measures

4.1 Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

4.2 Skin: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

4.3 Eyes: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

4.4 Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.5 Most important symptoms and effects, both acute and delayed
For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Section 5. Fire-fighting Measures

5.1 General Information: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

5.2 Extinguishing Media: Use carbon dioxide, dry chemical, or water spray

5.3 Fire/Explosion Hazard: Formation of toxic gases is possible during heating or fire.

5.4 NFPA Rating: Not Known

Section 6. Accidental Release Measures

6.1 General Information: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel

6.2 Major/Minor Spills: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release

Section 7. Handling and Storage

7.1 Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

7.2 Storage: Store as directed by product packaging.

7.3 Storage incompatibility: Keep away from direct sunlight

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

Components with workplace control parameters

Exposure limits	Issuer	OEL
Compound Nitroglycerin	ACGIH (TWA)	0.05 PPM

ACGIH - Skin Absorption Designation Skin - potential significant contribution to overall exposure by the cutaneous route

8.2 Exposure controls:

Appropriate engineering controls
Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye protection: Wear safety glasses or goggles if eye contact is possible.

Skin protection: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Hand protection: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Solid
Appearance	:	White tablet
Colour	:	White
pH Value	:	Not Known
Vapor Pressure	:	Not Known
Vapor Density	:	Not Known
Evaporation Rate	:	Not Known
Other information		
Flash point	:	Not Known
Molecular Weight	:	Not Known
Melting point/range	:	Not Known
Boiling point/boiling range	:	Not Known

Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Not Known
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron)	:	Not Known

9.2 Other Information

Not Known

Section 10. Stability and Reactivity

10.1 Reactivity: Not Known

10.2 Chemical stability: Stable under normal conditions of use.

10.3 Conditions to Avoid: Heat, moisture

10.4 Incompatibilities with Other Materials: As a precautionary measure, keep away from strong oxidizers.

10.5 Hazardous Decomposition Products: Formation of toxic gases is possible during heating or fire.

10.6 Hazardous Polymerization: Will not occur under.

Section 11. Toxicological Information

11.1 Information on toxicological effects

Acute Toxicity

	Dose	Route	Species	Dosage
Nitroglycerin	LD50	Oral	Rat	105 mg/kg
	LD50	Oral	Mouse	115 mg/kg
	LD50	Dermal	Rabbit	>280 mg/kg
	LD50	Dermal	Rat	>29 mg/kg
	LD50	IV	Rat	23.2 mg/kg

Section 12. Ecological Information

12.1 Toxicity: Based on the concentration of the active ingredient in the formulation, No harmful effects to aquatic organisms are expected.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
Nitroglycerin
Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 1.91 mg/L

In Vitro Cytogenetics Rat Negative
Midge LC50 48 Hours 20 mg/L

12.2 Persistence and degradability: Not Known

12.3 Bioaccumulative potential: Not Known

12.4 Mobility in soil: Not Known

12.5 Other: Not Known.

Section 13. Disposal Considerations

13.1 Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14. Transport Information

14. 1 Special precautions for user:

The following refers to all modes of transportation unless specified below.
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Canada - WHMIS: Classifications WHMIS hazard class:
Class D, Division 2, Subdivision B

Nitroglycerin

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	10 lb 4.54 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS/ELINCS List	200-240-8

Section 16. Additional Information

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
Explosives-Unstable explosives; H200 - Unstable explosive
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin
Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects
E - Explosive
T+ - Very toxic
N - Dangerous for the environment
R 3 - Extreme risk of explosion by shock, friction, fire or other sources of ignition.
R33 - Danger of cumulative effects.

R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Revision: First revision due to change in Section 3 & 8 and Second revision due to change in Title name.

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 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.

Compiled By (R & D)	Approved by (EHS Head)
Sanjeet 20-09-2017	20/09/2017
Signature /Date	Signature /Date

SAFETY DATA SHEET

Issuing Date 08-Nov-2017 **Revision Date** 08-Nov-2017 **Revision Number** 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name **Albuterol Sulfate HFA Inhalation Aerosol**
Active Ingredient Albuterol Sulfate

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Pharmaceutical
Uses advised against Other than Relevant Use

1.3. Details of the supplier of the safety data sheet

Manufacturer, Supplier TEVA
1090 Horsham Road
North Wales, PA 19454
BUSINESS PHONE: 215-591-3000 [08:00 AM --> 05:00 PM]

For further information, please contact
E-mail Address TevaSDSRequest@tevapharm.com

1.4. Emergency Telephone Number

Emergency Telephone Number United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]
International: 01-703-527-3887 (Chemtrec) [24-hours]

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Exempt from requirements - regulated as a medicinal product.

2.2. Label Elements

Exempt from requirements - regulated as a medicinal product

2.3. Other hazards

Pressurized container: May burst if heated

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Chemical Name	EC No	REACH Reg. No	CAS-No	Weight %
Albuterol Sulfate	-	Not available	51022-70-9	Proprietary
Excipients	-	Not available	-	Remainder

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact	Flush eyes with water for at least 15 minutes. Get medical attention if eye irritation develops or persists.
Skin Contact	Wash off immediately with plenty of water. Get medical advice/attention if you feel unwell.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Get medical advice/attention if you feel unwell.
Inhalation	Remove person to fresh air. If signs/symptoms continue, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

See product insert.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO_2). Foam. Dry powder. Halons.

Unsuitable extinguishing media

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Pressurized container: May burst if heated.

5.3. Advice for firefighters

Special protective equipment for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid all unnecessary contact.

6.1.1. For non-emergency personnel

Protective equipment See section 8

Emergency procedures Evacuate the danger area and alert emergency team

6.1.2. For emergency responders

See section 8

6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

6.3.1. Methods for Containment

No information available.

6.3.2. For cleaning up

Take up mechanically and collect in suitable container for disposal.

6.3.3. Other information

No information available

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for Safe Handling

Handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with: label.

7.3. Specific end use(s)

Exposure Scenario	No information available.
Other Guidelines	No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits	Not Determined: Mixture
Biological occupational exposure limits	No information available.
Derived No Effect Level (DNEL)	No information available.
Predicted No Effect Concentration (PNEC)	No information available.

8.2. Exposure controls

Engineering Measures	Provide engineering control.
Personal protective equipment	
Eye/face protection	Use eye protection appropriate for the task.
Skin protection:	
- Body protection	Use protective clothing appropriate for the task.
- Hand protection	Use appropriate protective gloves.
Respiratory Protection	Use appropriate respiratory protection.
Environmental exposure controls	No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	No information available
Physical State	Aerosol, Aerosol dispensers
Flash Point	No information available

9.2. Other information

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity
No information available.

10.2. Chemical Stability
Stable under normal conditions.

10.3. Possibility of hazardous reactions
None known.

10.4. Conditions to avoid
Heat, flames and sparks.

10.5. Incompatible materials.
None in particular.

10.6. Hazardous decomposition products
None under normal use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

acute toxicity	No hazard expected under normal handling conditions.
skin corrosion/irritation	No hazard expected under normal handling conditions.
serious eye damage/irritation	No hazard expected under normal handling conditions.
respiratory or skin sensitization	No hazard expected under normal handling conditions.
germ cell mutagenicity	No hazard expected under normal handling conditions.
carcinogenicity	No hazard expected under normal handling conditions.
reproductive toxicity	No hazard expected under normal handling conditions.
STOT - single exposure	No hazard expected under normal handling conditions.
STOT - repeated exposures	No hazard expected under normal handling conditions.
aspiration hazard	No hazard expected under normal handling conditions.

Other Information
No hazard expected under normal handling conditions. .

SECTION 12: Ecological information

12.1. Toxicity
Ecotoxicity effects
No information available.

12.2. Persistence and degradability
No information available.

12.3. Bioaccumulative potential
No information available.

12.4. Mobility in soil
No information available.

12.5. Results of PBT and vPvB assessment
No information available.

12.6. Other adverse effects
None known

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from Residues/Unused Products Dispose of in accordance with local regulations.

Contaminated Packaging Empty containers should be taken for local recycling, recovery or waste disposal.

SECTION 14: Transport information

No dangerous good in sense of these transport regulations

14.1.

UN-No -

14.2.

Proper Shipping Name -

14.3. Transport hazard class(es)

ADR / RID / ADN (land transport) -

IMDG (sea transport) -

IATA / ICAO (air transport) -

14.4.

Packing Group -

14.5. Environmental hazards

Marine Pollutant -

14.6. Special precautions for user

Emergency No. -

ADR/RID-Labels -

14.7.

Tecnical name -

Ship type -

Annex II -

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of: GHS

15.2. Chemical Safety Assessment

No information available

SECTION 16: Other information

CLP/GHS - Regulation

Hazard Statements

Training appropriate for workers is required to ensure protection of human health and environment.

Source of data

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES
A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS
H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK
N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
N.T.P. - NATIONAL TOXICOLOGY PROGRAM
I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
ECHA (European chemicals agency) databases
FDA (Food & Drug administration) database
EMA (European Medicines agency) documents
ChemAdvisor
Chemspider database

Issuing Date 08-Nov-2017
Revision Date 08-Nov-2017
Revision Note
Not applicable
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

SAFETY DATA SHEET

Diphenhydramine Hydrochloride Injection, USP

WEST-WARD

Section 1. Identification

GHS product identifier : Diphenhydramine Hydrochloride Injection, USP

Synonyms : None.

Product code : NDC 0641-0376-25, NDC 0641-0376-21

Chemical family : Antihistaminic agent.

Product type : Regulated prescription drug.

Container information : 1 ml vials.

Relevant identified uses of the substance or mixture and uses advised against

Pharmaceuticals.

Supplier's details : WEST-WARD PHARMACEUTICALS
EATONTOWN, NJ 07724

Emergency telephone number (with hours of operation) : CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3877

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : None.

CAS number/other identifiers

Section 3. Composition/information on ingredients

Ingredient name	%	CAS number
Water	60 - 100	7732-18-5
Diphenhydramine Hydrochloride	1 - 5	147-24-0
Benzethonium Chloride	0 - 0.1	121-54-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
halogenated compounds

Special protective actions for fire-fighters : No special protection is required.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Spill : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8).

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

Section 7. Handling and storage

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls : No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Appearance

Physical state	:	Liquid. [Aqueous solution.]
Color	:	Colorless.
Odor	:	Not available.
Odor threshold	:	Not available.
pH	:	4 to 6.5
Melting point	:	Not available.
Boiling point	:	Not available.
Flash point	:	Not applicable.
Burning time	:	Not applicable.
Burning rate	:	Not applicable.
Evaporation rate	:	Not available.
Flammability (solid, gas)	:	Not available.
Lower and upper explosive (flammable) limits	:	Not available.
Vapor pressure	:	Not available.
Vapor density	:	Not available.
Relative density	:	Not available.
Solubility	:	Not available.
Solubility in water	:	Not available.
Partition coefficient: n-octanol/water	:	Not available.
Auto-ignition temperature	:	Not available.
Decomposition temperature	:	Not available.
SADT	:	Not available.
Viscosity	:	Not available.

Section 10. Stability and reactivity

Reactivity	:	No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	:	The product is stable.
Possibility of hazardous reactions	:	Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	:	No specific data.
Incompatible materials	:	Reactive or incompatible with the following materials: oxidizing materials and acids.
Hazardous decomposition products	:	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Diphenhydramine Hydrochloride	LD50 Oral	Rat	500 mg/kg	-

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Section 11. Toxicological information

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	10000 mg/kg

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

Soil/water partition coefficient (K_{OC}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption**: Not determined

United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Section 15. Regulatory information

Classification : Not applicable.

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Diphenhydramine Hydrochloride	1 - 5	No.	No.	No.	Yes.	No.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

No products were found.

International regulations

International lists : **Australia inventory (AICS)**: All components are listed or exempted.
China inventory (IECSC): Not determined.
Japan inventory: All components are listed or exempted.
Korea inventory: Not determined.
Malaysia Inventory (EHS Register): Not determined.
New Zealand Inventory of Chemicals (NZIoC): All components are listed or exempted.
Philippines inventory (PICCS): Not determined.
Taiwan inventory (CSNN): Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

Section 16. Other information

History

Date of issue mm/dd/yyyy : 06/15/2013

Version : 1

Revised Section(s) : Not applicable.

Prepared by : KMK Regulatory Services Inc.

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

Section 16. Other information

UN = United Nations

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.
Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

SECTION 01 – IDENTIFICATION

BPI Labs, LLC
Freehold, NJ 07728 USA

Telephone: 1-727-471-0850

Product Name: Epinephrine Injection, USP 1 mg / mL (1:1,000) Ampule for Intravenous Infusion

Synonyms: None

Therapeutic Use: Epinephrine is an alpha and beta adrenergic agonist indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

Description: Sterile aqueous solution that is colorless and nonpyrogenic. Preservative free, contains no sulfites. Solutions for intravenous use should be inspected visually for particulate matter and discoloration, whenever solution and container permit. Do not use if discolored or precipitated.

SECTION 02 – HAZARD(S) IDENTIFICATION

Eye: Causes irritation of the eye. Signs / symptoms may include redness, watering, and itching.

Skin: Causes irritation of the skin. Signs / symptoms may include localized redness, swelling, itching, and dryness. May be absorbed through skin and cause target organ effects.

Inhalation: May cause irritation of respiratory tract.

Ingestion: May cause irritation of the gastrointestinal tract.

SECTION 03 – COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Ingredient	CAS Number	Amount
Epinephrine base (as the hydrochloride)	51-43-3	1 mg
Sodium Chloride	7647-14-5	9 mg
Hydrochloric Acid	7647-01-0	Used for pH adjustment
Water for Injection	7732-18-5	qs

SECTION 04 – FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin: Wash skin with soap and water. Remove contaminated clothing and shoes. Wash clothing and thoroughly clean shoes before reuse. If irritation occurs or persists, get medical attention.

Inhalation: Remove to fresh air. If not breathing, start basic life support. Get medical attention immediately.

Ingestion: If ingestion occurs, flush mouth out with water and get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 05 – FIRE FIGHTING MEASURES

General Hazard: Not known.

Fire Fighting Instructions: Wear approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

Extinguisher to Use: Use carbon dioxide, dry chemical, foam, or water spray.

Flash Point: Not known.

Auto-ignition: Not known.

Flammability Limits: Not known.

Hazardous Combustion Products: Ordinary combustible material.

Minimum Explosive Concentration for Dust / Vapor: Not known.

SECTION 06 – ACCIDENTAL RELEASE MEASURES

Occupational Spill: Contain the source of spill or leak. Use an inert absorbent material for aqueous solutions to clean affected area and place in a labeled container for recovery or disposal. Clean spill area thoroughly with detergent and water.

Clean-up – Large Spill: Review Sections 02 and 08 for proceeding with the clean up. Contain the source of the spill or leak. Eliminate possible ignition sources and follow appropriate grounding procedures. Use an inert absorbent material for aqueous solutions to clean affected area and place in a labeled container for recovery or disposal. Close container and move it to a secure holding area. Clean spill area thoroughly with detergent and water. Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal. Large spills may be subject to EPA/CERCLA Section 103 Release Report Requirements.

SECTION 07 – HANDLING AND STORAGE

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and / or vapors associated with product. Use with adequate ventilation.

Storage: Protect from light until ready to use. Do not refrigerate. Protect from freezing. Protect from alkalis and oxidizing agents.

Temperature Range: Store at room temperature, between 20°C to 25°C (68°F to 77°F).

SECTION 08 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Information: None established.

Ventilation: General room ventilation is adequate unless the process generates airborne dust or fumes.

Eye Protection: Wear ANSI approved chemical splash goggles or safety glasses.

Skin Protection: None required under normal and foreseeable conditions of use. Use coverall for clean up activities.

Hand Protection: Wear nitrile or latex gloves.

Respiratory Protection: None required under normal and foreseeable conditions of use. Use dust mask or approved respirator for dusty condition or when required.

SECTION 09 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Form:	Liquid solution.
Color:	Colorless.
Odor:	Odorless.
Molecular Weight:	183.2
Molecular Formula:	$C_9H_{13}NO_3$
pH:	2.2 to 5.0
Melting Point:	Not applicable.
Vapor Pressure:	Approximate to water.
Water Solubility:	Not applicable.
Solvent Solubility:	Aqueous solution.

SECTION 10 – STABILITY AND REACTIVITY

Reactivity:	Stable.
Conditions to Avoid:	Do not mix with other drugs. Exposure to light.
Incompatibilities:	None known.
Hazardous Polymerization:	Will not occur.
Hazardous Decomposition Products:	No data available. See section 05 under Hazardous Combustion Products.
Oxidizing Properties:	No data available.
Explosive Properties:	None known or expected.

SECTION 11 – TOXICOLOGICAL INFORMATION

Adequate carcinogenesis studies have not been reported. An equivocal response of epinephrine was found when tested in Salmonella typhimurium strain TA 100 in the absence of metabolic activation system (S9) and negative In the presence of activation system (S9).

There are no data from either animal or human studies regarding potential for the impairment of fertility.

Epinephrine was associated with metabolic effects, decreased mesenteric, coronary and renal conductance in a sheep model of septic shock. Data from hemolysis study have shown that epinephrine at 1:1,000 dilution is non-hemolytic. Epinephrine infusion significantly increased the MAP (69 vs. 86 mmHg) and cardiac output (6.4 vs. 7.1 L/min) and decreased renal blood flow (330 vs. 247 mL/min).

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview: No relevant studies identified.

SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal Procedure: Incineration is the recommended means of disposal for this material. This material may also be disposed in landfills. Federal, State, Local environmental regulations and Site conditions may affect proper disposal.

SECTION 14 – TRANSPORT INFORMATION

Proper Shipping Name: Epinephrine Injection, USP 1 mg / mL (1:1,000)

General Shipping Instructions: Non-regulated.

SECTION 15 – REGULATORY INFORMATION

No data available.

State Right to Know: Refer to applicable state to determine applicability.

SECTION 16 – OTHER INFORMATION

Disclaimer: BPI Labs, LLC believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.