

MATERIAL SAFETY DATA SHEET

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Twinject[®] Auto-Injector

Common Name: Epinephrine Auto-Injector, Epinephrine 1:1000

United States (US) Product Code(s):
 59630-801-01 Twinject[®] 0.15 mg, Single, US
 59630-801-02 Twinject[®] 0.15 mg, Two-Pack, US
 59630-800-01 Twinject[®] 0.3 mg, Single, US
 59630-800-02 Twinject[®] 0.3 mg, Two-Pack, US
 20010 CPJT Cartridge (Epinephrine), US

Canadian (CDN) Product Code(s):
 02268205 Twinject[®] 0.15 mg, Single, CDN
 02247310 Twinject[®] 0.30 mg, Single, CDN
 31114 CPJT Cartridge (Epinephrine), CDN

Product Use: Emergency treatment of anaphylaxis

Sciele Pharma, Inc. 5 Concourse Parkway Ste 1800
Atlanta, GA 30328

Manufacturer
(CPJT epinephrine 1:1000) Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045, USA

Assemblers Phillips Plastic Corporation
428 Technology Drive
Menomonie, WI 54571 USA

Transportation Emergency:

Non-Transportation Emergency:

CHEMTREC: (800) 424-9300
DISTRICT OF COLUMBIA: (202) 483-7616

Sciele Pharma, Inc. CONTACT INFORMATION:
(800) 849-9707 X 1454

SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Substance Class	Chemical Formula	M.W.	Concentration (mg/mL)	Chemical Abstract Society (CAS) #
1-(3,4-dihydroxyphenyl)-2-methylaminoethanol (Epinephrine)	Sympathomimetic catecholamine, vasoconstrictor	C ₉ H ₁₃ NO ₃	183.21	1.0	51-43-4
Sodium bisulfite	Sulfites	NaHSO ₃	104.06	~1.5	7631-90-5
Chlorobutanol	alcohol	C ₄ H ₉ Cl	177.46	~4.8	57-15-8

MATERIAL SAFETY DATA SHEET

SECTION 3. HAZARDS IDENTIFICATION

Emergency Overview: This product has been approved for specific unit dosage identified on the package insert. Use only as directed by this information.

Over dosage of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients.

Adverse reactions to epinephrine include transient, moderate anxiety; apprehensiveness; restlessness; tremor; weakness; dizziness; sweating; palpitations; pallor; nausea and vomiting; headache, and/or respiratory difficulties. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension of hyperthyroidism. Large doses of epinephrine can cause acute hypertension. Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs. Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease. Angina may occur in patients with coronary artery disease.

SECTION 4. FIRST AID MEASURES

Skin Contact:

Wash affected areas with soap and water after removing contaminated clothing. Obtain medical attention if contamination is significant and/or a skin reaction is evident.

Eye Contact:

Flush affected eye(s) with large amounts of cool potable water for at least 15 minutes. Obtain medical attention. If irritation persists or sign signs of toxicity occur, seek medical attention.

Injection:

Accidental injection into the hands or feet may result in loss of blood flow to the affected area and should be avoided. If there is an accidental injection into these areas, advise patient to go immediately to the nearest emergency room for treatment.

Ingestion:

If individual is conscious, rinse mouth with water. Never give anything by mouth to an unconscious person or to any individual having convulsions. If signs of toxicity occur, seek medical attention.

Inhalation:

N/A

SECTION 5. FIRE FIGHTING MEASURES

Flashpoint (C°)	Non-Flammable
Flammable Limits (% by volume)	Not applicable
Auto ignition Temperature	Not applicable
Extinguishing Media:	Use media appropriate for primary cause of fire
Firefighting Procedures:	Wear full protective clothing and use self-contained breathing apparatus (SCBA) in the event of fire where bulk quantities are stored.

MATERIAL SAFETY DATA SHEET

SECTION 6. ACCIDENTAL RELEASE MEASURES

Clean up with soap and water. For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, collect spillage by sweeping up spilled material, and place in labeled, sealed container for proper disposal.

SECTION 7. HANDLING AND STORAGE

Store at Room Temperature (min\max): excursion 15-30° C or 68-77° F
Shelf Life: refer to expiration date on package
Special Sensitivity: Protect from Light
Handling Storage Precautions: DO NOT Refrigerate or Freeze

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Specific Engineering Controls (such as ventilation):	NONE
Eye Protection Requirements:	Safety Glasses
Skin Protection Requirements:	Latex / Nitrile / Rubber
Respiratory Requirements:	NONE
Work Practices:	NONE
Additional Protective Measures:	NONE

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form: Liquid	pH: 2.2-5.0	Specific Gravity (H ₂ O =1): ~1
Appearance: Clear liquid	Boiling Point: N/A	Bulk Density: 1.008
Color: Clear	Melting/Freeze Point: N/A	Vapor Pressure: N/D
Odor: None	Solubility in Water: Complete	Evaporation Rate: N/D

N/A = Not applicable N/D= Not Determined

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable
Incapability: None
Hazardous Decomposition: None
Conditions to Avoid: Contact with strong acids, bases or oxidizers. Epinephrine deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin.

SECTION 11. TOXICOLOGICAL INFORMATION

Dose Toxicity: Over dosage of epinephrine may produce extremely elevated blood pressure, which may result in cerebrovascular hemorrhage. Overdose may also cause transient bradycardia followed by tachycardia and these may be accompanied by potentially fatal cardiac arrhythmias.

Carcinogenicity or Mutagenicity: There are no data from either animal or human studies regarding the carcinogenicity or mutagenicity of Epinephrine.

Teratogenicity: Pregnancy Category C - Epinephrine has been shown to have developmental effects in rabbits at a subcutaneous dose of 1.2 mg/kg (approximately 30 times the maximum

MATERIAL SAFETY DATA SHEET

recommended daily subcutaneous or intra muscular dose on a mg/m² basis), in mice at a subcutaneous dose of 1 mg/kg approximately 7 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis) and in hamsters at a subcutaneous dose of 0.5 mg/kg approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis).

Reproductive Effects: Not determined

Other component toxicological Information available for Epinephrine:

Pharmacological Activity: Epinephrine is a sympathomimetic drug, acting on both alpha and beta receptors. It is the drug of choice for the emergency treatment of severe allergic reactions (Type I) to insect stings or bites, foods, drugs and other allergens.

SECTION 12. ECOLOGICAL INFORMATION

Data not yet available

SECTION 13. DISPOSAL CONSIDERATIONS

Dispose of material in accordance with local, state, Federal and/or Country regulations.

SECTION 14. TRANSPORT INFORMATION

Technical Shipping Name: Hazardous Waste Liquid NOS (Contains Epinephrine)

Hazard Class: 9

DOT I.D. Number: NA3082

Packing Group Number: PGIII

SECTION 15. REGULATORY INFORMATION

OSHA STATUS: This product is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

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

CERCLA REPORTABLE QUANTITY: Not Applicable

SARA TITLE III:

SECTION 302 EXTREMELY

HAZARDOUS SUBSTANCES: Not Applicable

SECTION 311/312

HAZARDOUS CATEGORIES: Not Applicable

SECTION 313

TOXIC CHEMICALS: Not Applicable

RCRA STATUS: This material is a listed hazardous waste; EPA Number: P042

SECTION 16. OTHER INFORMATION

Sciele's method of hazard communication is comprised of Product Labels and Material Safety Data Sheets.

HMIS Ratings:		Health	Flammability		Reactivity
		1	0		0

0= Minimal

1= Slight

2= Moderate

3=Severe