



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

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Material Name: Ceruletide Diethylamine for Injection

Trade Name: TAKUS(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for gastrointestinal disorders, diagnostic aid.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS List	%
Mercaptosuccinate	70-49-5	200-736-4	*
Ceruletide Diethylamine	71247-25-1	275-298-0	<0.1
Water for injection	7732-18-5	231-791-2	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Powder with a clear Liquid in glass ampules or vials

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. May cause low blood pressure and dizziness.

EU Indication of danger: Not classified

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

4. FIRST AID MEASURES

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Eye Contact:	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
Skin Contact:	Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.
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.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	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.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:	Avoid inhalation and contact with skin, eye, and clothing. Wash thoroughly after handling.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands:	Wear protective gloves when working with large quantities.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.

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Respiratory protection: Respiratory protection is not expected to be necessary under normal handling conditions; required only if dust is generated. In dusty conditions use an approved dust mask or more protection as needed.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Powder	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the active ingredient.

Acute Toxicity: (Species, Route, End Point, Dose)

Ceruletide Diethylamine

Rat	Subcutaneous	LD 50	> 1000 mg/kg
Rat	Intravenous	LD 50	714 mg/kg
Mouse	Subcutaneous	LD 50	> 1000 mg/kg
Mouse	Intravenous	LD 50	1012 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Ceruletide Diethylamine

35 Day(s)	Rat	Subcutaneous	3500 mg/kg/day	LOEL	Pancreas
26 Week(s)	Rat	Intramuscular	2730 µg/kg/day	LOEL	Pancreas
26 Week(s)	Dog	Intramuscular	2730 µg/kg/day	LOEL	Pancreas

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Ceruletide Diethylamine

Embryo / Fetal Development	Rat	Subcutaneous	300 ug/day	NOEL	Not teratogenic
Embryo / Fetal Development	Rabbit	Intramuscular	300 ug/day	NOEL	Not Teratogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

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13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Mercaptosuccinate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-736-4

Ceruletide Diethylamine

EU EINECS List	275-298-0
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Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 13 - Disposal Considerations.

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Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet