MATERIAL SAFETY DATA SHEET

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

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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Ceruletide for Oral Solution

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ceruletide Diethylamine	71247-25-1	275-298-0	5ug, 40ug
Sodium hydroxide	1310-73-2	215-185-5	###

Ingredient	CAS Number	EU EINECS List	%
Mercaptosuccinate	70-49-5	200-736-4	*
Water for injection	7732-18-5	231-791-2	###

Additional Information:
* Proprietary
as required
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Solution

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

Additional Hazard Information:
Short Term: May cause irritation : eye, skin (based on components) . Acute toxicity following ingestion is not expected.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on pancreas.
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

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: Not determined

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 spill with absorbent material. 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 at controlled room temperature. Protect from light.

Storage Temperature: < 25 °C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sodium hydroxide

OSHA - Final PELS - TWAs:	2 mg/m³
ACGIH Ceiling Threshold Limit:	= 2 mg/m^3 Ceiling
Australia PEAK	= 2 mg/m^3 Peak

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:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Wear protective clothing when working with large quantities.
Respiratory protection:	Under normal conditions of use, respiratory protection is not expected to be necessary. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Solution	**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:	No reactions identified

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

Sodium hydroxide
Mouse IP LD50 40 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.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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.

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.

Ceruletide Diethylamine

EU EINECS List	275-298-0

Sodium hydroxide

CERCLA/SARA Hazardous Substances	= 1000 lb final RQ
and their Reportable Quantities:	= 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 5
for Drugs and Poisons:	Schedule 6
EU EINECS List	215-185-5

Mercaptosuccinate

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

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 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet