Material Safety Data Sheet

Authorization date: 07/28/1999
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Version: 1

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

Product name: Complete Protease Inhibitor Cocktail Tablets
Product number: 1697498
Global material number: 11697498001
Business area: Roche Applied Sciences
Product line: Not applicable
Instrument type: Not applicable

Supplier:
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
Site Phone Number: 1-800-428-5074

Emergency telephone number:
CHEMTREC:
1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description 1: Bottle 1

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
Mannitol	87-78-5	40-50	NA	NA	NA	NA
EDTA, disodium salt	139-33-3	<25	NA	NA	NA	NA
Pefabloc	34284-75-8	10 - 20	NA	NA	NA	NA
Polyvinylpyrrolidone	9003-39-8	1-5	NA	NA	NA	NA
Polyethylene glycol	25322-68-3	1-5	NA	NA	NA	NA

3. HAZARDS IDENTIFICATION

Emergency Overview

NFPA Ratings: Health= 1 Flammability= 0 Reactivity= 0 Special= I

Special Definitions: A=Allergen CA=Carcinogen CO=Corrosive F=Flammable H=Harmful I=Irritant Ox=Oxidizer PB=Potential Biohazard R=Reproductive S=Sensitizer T=Toxic T+=Highly Toxic W=Water Reactive

Principle routes of exposure: Ingestion, skin and/or eye contact.

Inhalation: None.

Ingestion: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Skin contact: None.

Eye contact: May cause irritation.

Sensitization or Odor threshold: None.

Medical conditions aggravated by exposure: None known

Additional information: None

4. FIRST AID MEASURES

Inhalation: Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

Ingestion: Call a physician immediately. Do not induce vomiting without medical advice.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Notes to physician: None determined

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO_2, water spray or "alcohol" foam.

Unusual hazards: None known.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Evacuate personnel to safe areas. Remove all sources of ignition.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system. Do not let product enter drains.

Methods for cleaning up: Never return spills in original containers for re-use. Soak up with oil absorbent material. Sweep up or vacuum (if powder) or soak up with inert absorbent material (if liquid), then place into a suitable clean, dry, closed container, and label for disposal.

7. HANDLING AND STORAGE

Handling: Protect from contamination. Wear personal protective equipment.

Storage: No special precautions required.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering measures: Not applicable.

Personal Protective Equipment

Respiratory protection: Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation, 29CFR1910.134. Always use a NIOSH approved respirator when necessary.

Hand protection: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Skin and body protection: Wear appropriate body protection to prevent skin contact.

Eye protection: Wear appropriate eye protection to prevent eye contact.

Hygiene measures: When using, do not eat, drink or smoke. Keep away from food and drink. Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: White.
Odor: None.
Physical state: Solid.
Solubility in water: Soluble.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.
Polymerization: None under normal processing.
Hazardous decomposition products: No data available.
Materials to avoid: Incompatible with strong acids and bases. Oxidising agents (strong).

11. TOXICOLOGICAL INFORMATION

Description 1: Bottle 1

11. TOXICOLOGICAL INFORMATION

Components	NIOSH - Selected LD50s and LC50s:	NIOSH Pocket Guide - Target Organs:
EDTA, disodium salt	= 2 g/kg Oral LD50 Rat = 2050 mg/kg Oral LD50 Mouse	
Polyvinylpyrrolidone	= 100 g/kg Oral LD50 Rat > 40 g/kg Oral LD50 Mouse	
Polyethylene glycol	= 28 g/kg Oral LD50 Rat = 34 g/kg Oral LD50 Mouse > 20 g/kg Dermal LD50 Rabbit	

Inhalation: No additional data available
Skin: No additional data available
Oral: No additional data available
Mutagenic effects: No data is available on the product itself
Reproductive toxicity: No data is available on the product itself
Carcinogenic effects:

Components	IARC Group 1	IARC Group 2A or 2B	IARC Group 3 or 4	NTP	OSHA Select Carcinogens	EPA IRIS Carcinogen Assessment
Polyvinylpyrrolidone			Monograph 71, 1999; Supplement 7, 1987; Monograph 19, 1979			

12. ECOLOGICAL INFORMATION

Bioaccumulation: No data available

Aquatic toxicity: Not applicable

Ecotoxicity effects: No data is available on the product itself

Components	Ecotoxicity - Fish Species Data	Ecotoxicity - Microtox Data	Ecotoxicity - Water Flea Data	Ecotoxicity - Freshwater Algae Data
EDTA, disodium salt	= 159 mg/L LC50 bluegill 96 h Static			
Polyethylene glycol	> 5000 mg/L LC50 goldfish 24 h PEG 200, 400, 800	= 100,000 mg/L EC50 Photobacterium phosphoreum 15 min polymer unspecified		

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous.

14. TRANSPORT INFORMATION

Is product hazardous to ship? No

DOT

Proper shipping name: None			
UN Number: Not applicable	**Hazard class:** Not applicable	**Subsidiary risk:** Not applicable	**Packing group:** Not applicable

ICAO/IATA

Proper shipping name: None			
UN Number: Not applicable	**Hazard class:** Not applicable	**Subsidiary risk:** Not applicable	**Packing group:** Not applicable

15. REGULATORY INFORMATION

U.S. Regulations:

U.S. CERCLA/SARA/TSCA Regulatory Information: The following chemicals are listed under the following TSCA/SARA/CERCLA lists. Refer to TSCA regulation if you need a definition for acronyms that may be shown in the TSCA Inventory field in the table below

Components	CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)	CERCLA/SARA 304 RQ (40 CFR Table 302.4)	SARA 313 Emission reporting	TSCA Inventory
Mannitol				Present
EDTA, disodium salt				Present
Polyvinylpyrrolidone				XU
Polyethylene glycol				XU

U.S. Clean Water Act (CWA)/ California Proposition 65: The following chemicals are listed under the CWA and/or California Proposition 65:

Canadian Regulations:

Canada DSL Inventory List - This product does not comply with DSL
Canada NDSL Inventory List - This product does not comply with NDSL

Components	Canada - WHMIS: Classifications of Substances:
EDTA, disodium salt	Uncontrolled product according to WHMIS classification criteria.
Polyvinylpyrrolidone	Uncontrolled product according to WHMIS classification criteria.
Polyethylene glycol	D2B

16. OTHER INFORMATION

Reason for revision: A component has been added to the formulation. SEE SECTION 2
References: (1) Abendroth VK: Ausgezeichnete Wirksakeit der Natriumzitrat- EDTA-Kombinationstherapie bei schwerer Bleivergiftung in der Schwangerschaft. Dtsch Ges Wissen 26:2130-1, 1971. 2) Timpo AE et al: Congenital lead intoxication. J Pediatr 94:765-7, 1979.
Additional advice: None
Prepared by: Roche Diagnostics, Health & Safety Department, MSDS Contact: 317-521-7425 or 317-521-7505

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End of Safety Data Sheet