

MATERIAL SAFETY DATA SHEET

Product Name: **Calypte HIV-1 BED Incidence EIA**
Product Number: **98003**
Manufacturing Company: **Calypte Biomedical Corporation**
Five Centerpointe Drive, Suite 400
Lake Oswego, OR 97035
Customer Service **971-204-0282**
Technical Phone: **360-694-5900**
Technical Fax: **360-694-7520**
Emergency Phone: **800-424-9300 (CHEMTREC)**

The Calypte HIV-1 BED Incidence EIA is comprised of two subunits:

PN 88004: Freezer Pack

PN 88005: Refrigerator Pack

The hazardous materials present in the kit components of each subunit will be addressed separately.

A summary of all components containing materials that are hazardous in concentrated form is presented on page 13.

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PN 88004: Freezer Pack Subunit

Subcomponents:

PN 80443	1000x Streptavidin HRP	50µL
PN 80444	1000x BED peptide	50µL
PN 80445	Low Positive Control	100µL
PN 80446	Calibrator	100µL
PN 80447	Negative Control	100µL
PN 80448	High Positive Control	100µL

Hazardous substances:

I. 2-Methyl-4-Isothiazonlin-3-One (ProClin 950)

Molecular Formula: C₄H₄NOS

CAS # 2682-20-4

Manufacturer # 46884-U

Found in subcomponents: 80443, 8044, 80445, 80446, 80447, 80448

Percent as used in subcomponents: 0.0095%

A. SAFETY OVERVIEW:

In its concentrated form of 9.5%, this compound is: corrosive, causes burns, and may cause sensitization by skin contact. Concentrated material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin. Inhalation may result in spasm, inflammation and edema of exposed areas. Concentrated material may be harmful if swallowed. At the very dilute formulation of 0.0095% in volumes of 100µL or less, hazards are minimal. The information presented below is for the concentrated form.

B. RATINGS:

HMIS Rating

Health: 3

Flammability: 0

Reactivity: 0

NFPA Rating

Health: 3

Flammability: 0

Reactivity: 0

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C. EMERGENCY AND FIRST AID:

- Ingestion:** Do not induce vomiting. Wash mouth out with water provided person is conscious. Call a physician.
- Dermal Exposure:** Flush with copious amounts of water. Remove contaminated clothing and shoes. Call physician if burning occurs.
- Contact with Eyes:** Flush with copious amounts of water or eyewash saline for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call physician.
- Inhalation:** Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea, and vomiting. Remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. If discomfort persists, obtain medical attention.

D. HANDLING AND STORAGE: Do not breathe vapor. Do not get in eyes, on skin, on clothing. Avoid prolonged or repeated exposure. Keep container tightly closed. Store ProClin 950-containing components as recommended on label and/or product insert.

E. EXPOSURE CONTROLS: Wear chemical resistant gloves, safety goggles, face shield, gown.

F. STABILITY AND REACTIVITY: Material is stable. Avoid contact with strong oxidizing agents, amines, mercaptans, reducing agents. Hazardous decomposition products include carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides.

G. FIRE: Material is not flammable. Emits toxic fumes under fire conditions. Auto-ignition temp: N/A. Suitable Extinguishing Media: Carbon dioxide, dry chemical powder, or appropriate foam. Firefighting: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

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H. DISPOSAL: Concentrated ProClin 950 has special disposal considerations and a licensed professional waste disposal service should be contacted to dispose of this material. The ProClin 950 as part of the HIV-1 BED Incidence EIA should be disposed of consistent with the component in which it is present. Subcomponents 80443, 8044, 80445, 80446 contain human serum and should be disposed of with biohazardous waste. ProClin 950-containing subcomponents 80447, 80448 can be disposed normally with copious amounts of water. Observe all federal, state, and local environmental regulations. Dispose as biohazardous waste

I. TRANSPORT INFORMATION:

Road: DOT class:	NA
Remarks:	Not restricted for transportation
Sea: IMDG Class:	NA
Marine Pollutant:	No
Remarks:	Not restricted for transportation
Air: ICAO.IATA Class:	NA
Remarks:	Not restricted for transportation

II. Human Serum

Molecular formula: NA

CAS#: None

Manufacturer #: 30732, 60422, 60492, 60493, 60494, 60495

Found in subcomponents: 80445, 80446, 80447, 80448

Percentage as used in subcomponents: 100%

A. SAFETY OVERVIEW:

All human serum used in the product has been determined to be free of the presence of hepatitis B and C, and has been heat inactivated to render any HIV virus not viable. This is confirmed by infectivity testing. However, universal precautions should always be followed when working with any body fluid. Avoid contact with skin, mouth, and eyes. Wear gloves, safety glasses, and appropriate Personal Protection Equipment (PPE).

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B. RATINGS:

HMIS Rating

Health: NA Flammability: NA Reactivity: NA

NFPA Rating

Health: NA Flammability: NA Reactivity: NA

C. EMERGENCY AND FIRST AID:

Ingestion: Induce vomiting. Wash mouth out with water provided person is conscious. Call a physician.

Dermal Exposure: Wash exposed area with soap and copious amounts of water. Remove contaminated clothing and shoes.

Contact with Eyes: Flush with copious amounts of water or eyewash saline for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.

Inhalation: Non-volatile. No fume inhalation hazard.

D. HANDLING AND STORAGE: Treat as infectious and use universal precautions.

E. EXPOSURE CONTROLS: Wear gloves, safety glasses, gown, biohazardous shield.

F. STABILITY AND REACTIVITY: Material is stable and non-reactive.

G. FIRE: Material is not flammable. Extinguishing Media: Water spray, carbon dioxide, dry chemical powder, or appropriate foam. Special Procedure: None special. Unusual Fire Fighting Procedures: Wear protective clothing to prevent contact with skin and eyes.

H. DISPOSAL: Dispose as biohazardous waste.

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I. TRANSPORT INFORMATION:

Road: DOT class:	NA
Remarks:	Not restricted for transportation
Sea: IMDG Class:	NA
Marine Pollutant:	No
Remarks:	Not restricted for transportation
Air: ICAO.IATA Class:	NA
Remarks:	Not restricted for transportation

PN 88005: Refrigerator Pack Subunit

Subcomponents:

PN 20597	Product Insert	1 Insert
PN 110019	Plate Sealers	1 Pack
PN 80441	TMB	27 mL
PN 80438	10x Wash Buffer	350 mL
PN 80440	Stop Component	27 mL
PN 80439	BSA	6 grams
PN 80442	Coated Plates	2 Plates

Hazardous substances:

III. TMB Solution (contains 3, 3', 5, 5'-Tetramethylbenzidine, a non-carcinogenic analog of Benezidine)

Molecular Formula: Solution containing 3, 3', 5, 5'-Tetramethylbenzidine


CAS # None

Manufacturer #: TTMB

Found in subcomponent: 80441

Concentration as used in subcomponent: TMB Solution provided and used neat

A SAFETY OVERVIEW:

 B is solution containing 3, 3', 5, 5'-Tetramethylbenzidine which is a non-carcinogenic analog of Benezidine. The solution has mild oxidizing agent properties. Avoid contact with skin, eyes, inhalation, and ingestion. Toxicological properties have not been thoroughly investigated. Signs and symptoms of exposure are not known at this time. The information presented below is for the TMB solution as provided in the kit.

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B. RATINGS:

HMIS Rating

Health: 0 Flammability: 0 Reactivity: 1

NFPA Rating

Health: 0 Flammability: 0 Reactivity: 1

C. EMERGENCY AND FIRST AID:

Ingestion: Induce vomiting. Wash mouth out with water provided person is conscious. Call a physician.

Dermal Exposure: Wash exposed area with soap and copious amounts of water. Remove contaminated clothing and shoes and wash before reuse.

Contact with Eyes: Flush with copious amounts of water or eyewash saline for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers.

Inhalation: Remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. If discomfort persists, call a physician to obtain medical attention.

D. HANDLING AND STORAGE: Do not breathe vapor. Do not get in eyes, on skin, on clothing. Avoid prolonged or repeated exposure. Keep container tightly closed. Store TTMB-containing component as recommended on label and/or product insert.

E. EXPOSURE CONTROLS: Wear gloves, safety glasses or goggles, gown, shields.

F. STABILITY AND REACTIVITY: Stability: This product is stable. Protect from direct UV light, avoid elevated temperatures. Material is incompatible with Strong oxidizing agents, and metals. Hazardous polymerization will not occur. Hazardous decomposition is not known, possibly carbon monoxide and carbon dioxide.

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G. FIRE: Flash Point: N/A. Flammable Limits: N/A. Extinguishing Media: Water spray, carbon dioxide, dry chemical powder, or appropriate foam. Special Procedure: None special. Unusual Fire Fighting Procedures: None Special

H. DISPOSAL: Cover released or spilled with sand, vermiculite, or other absorbent. Use normal waste disposal with copious amounts of water; observe all federal, state, and local environmental regulations.

I. TRANSPORT INFORMATION:

Road: DOT class:	NA
Remarks:	Not restricted for transportation
Sea: IMDG Class:	NA
Marine Pollutant:	No
Remarks:	Not restricted for transportation
Air: ICAO.IATA Class:	NA
Remarks:	Not restricted for transportation

IV. 1N H₂SO₄ (1N Sulfuric Acid)

Molecular Formula: H₂SO₄

CAS #: 7664-93-9

Manufacturer #: H2SO4-1

Found in subcomponent: 80440

Concentration as used in subcomponent: 1 Normal

A. SAFETY OVERVIEW:

In its concentrated form, Sulfuric Acid is corrosive, reactive, and causes burns. The material provided in the HIV-1 BED Incidence EIA is significantly diluted and thus hazards are reduced. The information presented below is for the concentrated form.

Concentrated 1N H₂SO₄ is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin. Inhalation may result in spasm, inflammation and edema of the exposed areas. Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea, and vomiting.

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B. RATINGS:

HMIS Rating

Health: 3 Flammability: 0 Reactivity: 2

NFPA Rating

Health: 3 Flammability: 0 Reactivity: 2

C. EMERGENCY AND FIRST AID:

Ingestion: Do not induce vomiting. Wash mouth out with water provided person is conscious. Call a physician.

Dermal Exposure: Flush exposed area with copious amounts of water. Remove contaminated clothing and shoes and wash before reuse. Call a physician if burning occurs.

Contact with Eyes: Flush with copious amounts of water or eyewash saline for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.

Inhalation: Remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. If discomfort persists, call a physician to obtain medical attention.

D. HANDLING AND STORAGE: Released or Spilled Material: Cover with dry lime or soda ash. Ventilate area and wash spill site after material pickup is complete.

E. EXPOSURE CONTROLS: Wear gloves, safety glasses or goggles, gown, shields.

F. STABILITY AND REACTIVITY: Material is stable. Avoid moisture conditions. Avoid contact with these materials: bases, halides, organic materials incompatible with carbides, chlorates, fulminates, nitrates, picrates, cyanides, alkali halides, zinc iodide, permanganates, hydrogen peroxide, azides, perchlorates, nitromethane, phosphorous, and nitrates. Violent reaction with: cyclopentadiene,

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cyclopentanone, oxime, nitroaryl amines, hexalithium disilicide, and phosphorous (III) oxide, finely powdered metals.

G. FIRE: Flash Point: N/A. Flammable Limits: N/A
Extinguishing Media: Suitable: Noncombustible. Use extinguishing media appropriate to surrounding fire conditions. Unsuitable: Do not use water. Unusual Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Can emit toxic fumes under fire conditions.

H. DISPOSAL: Concentrated sulfuric acid with more than 51 percent acid has special disposal considerations and a licensed professional waste disposal service should be contacted to dispose of this material. The 1N H₂SO₄ as part of the HIV-1 BED Incidence EIA can be disposed of normally but with copious amounts of water. Observe all federal, state, and local environmental regulations.

I. TRANSPORT INFORMATION:

Road: DOT class:	8
Identification Number:	UN1760
Packing group:	III
Proper shipping name:	CORROSIVE LIQUID, N.O.S. SULPHURIC ACID
Sea: IMDG Class:	8
UN Number:	1760
Packing group:	III
Marine Pollutant:	No
Proper shipping name:	CORROSIVE LIQUID, N.O.S. SULPHURIC ACID
Air: ICAO.IATA Class:	8
UN Number:	1760
Packing group:	III
Proper shipping name:	CORROSIVE LIQUID, N.O.S. SULPHURIC ACID

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V. Albumin, Bovine Fraction V

Molecular Formula: NA

CAS #: 9048-46-8

Manufacturer #: A-3059

Found in: PN 80439 (also in small amounts in 80443 and 80444 of Freezer Pack)

Concentration as used in subcomponent (80439): 100%

A. SAFETY OVERVIEW:

Bovine Serum Albumin can be a mild irritant. Avoid inhalation, contact with eyes, skin and clothing.

B. RATINGS:

HMIS Rating

Health: 0

Flammability: 0

Reactivity: 0

NFPA Rating

Health: 0

Flammability: 0

Reactivity: 0

C. EMERGENCY AND FIRST AID:

Ingestion: Wash mouth out with water provided person is conscious.
Call a physician.

Dermal Exposure: Wash exposed area with soap and copious amounts of
water.

Contact with Eyes: Flush with copious amounts of water or eyewash saline
for at least 15 minutes. Assure adequate flushing by
separating the eyelids with fingers. Call a physician.

Inhalation: Remove to fresh air. If breathing is difficult, call a
physician.

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D. HANDLING AND STORAGE: For disposal of spills, sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

E. EXPOSURE CONTROLS: Wear gloves, safety glasses or goggles, gown.

F. STABILITY AND REACTIVITY: Material is stable and non-reactive. Store at 2-8°C to maintain product integrity.

G. FIRE:

Flash Point: N/A

Flammability: N/A

Extinguishing Media: Suitable: Water spray. Carbon dioxide, dry chemical power, or appropriate foam.

Unusual Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Can emit toxic fumes under fire conditions.

H. DISPOSAL: Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

I. TRANSPORT INFORMATION:

Road: DOT class:	NA
Remarks:	Not restricted for transportation
Sea: IMDG Class:	NA
Marine Pollutant:	No
Remarks:	Not restricted for transportation
Air: ICAO.IATA Class:	NA
Remarks:	Not restricted for transportation

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Summary of Components Containing Materials Hazardous in Their Concentrated Forms

<u>PN</u>	<u>Component Name</u>	<u>Material Hazardous in Conc. form.</u>
PN 80443	1000x Streptavidin HRP	I
PN 80444	1000x BED peptide	I
PN 80445	Low Positive Control	I, II
PN 80446	Calibrator	I, II
PN 80447	Negative Control	I, II
PN 80448	High Positive Control	I, II
PN 80441	TMB	III
PN 80440	Stop Component	IV
PN 80439	BSA	V

General Notes:

- Any material/component not described in this document is not considered to be hazardous in their concentrated forms nor as it is currently formulated for the Incidence EIA. This is based on evaluations made by Calypte Biomedical or the Manufacturer/Supplier of the subcomponent under the OSHA Hazard Communication Standard, 29 C.F.R. 1910.1200. Material Safety Data Sheets are required only for products containing hazardous ingredients at a concentration equal or greater than 1% and/or carcinogens at a concentration equal or greater than 0.1% (OSHA, 29 C.F.R. 1910.1200).
- It is advised that appropriate Personal Protection Equipment be employed at all times during the use of the HIV-1 BED Incidence EIA. This includes the use of safety glasses or goggles, biohazard shield or hoods, lab coats or gowns, and gloves. It is also advised that GLP/GMP and proper training be followed to further minimize the risk of accident and exposure.
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