

MATERIAL SAFETY DATA SHEET

SECTION 1 CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**GENETICS INSTITUTE,
INC.**

**87 Cambridge Park Drive
Cambridge, MA 02140**

(617) 876-1170

**24 HR. Emergency Medical
Information:**

610-688-4400

**CHEMTREC(R) USA, CAN, PR: 800-
424-9300**

International: 202-483-7616

SUBSTANCE: COAGULATION FACTOR IX (RECOMBINANT), BENEFIX(TM)

TRADE NAMES/SYNONYMS:

Coagulation Factor IX (Recombinant) is also known as Antihemophilic Factor B; 00225078

PRODUCT USE: pharmaceutical, indicated for the control of hemorrhagic episodes for hemophilia B patients

CREATION DATE: Apr 13 2000

REVISION DATE: Jun 17 2002

SECTION 2 COMPOSITION, INFORMATION ON INGREDIENTS

COMPONENT: GLYCINE

CAS NUMBER: 56-40-6

EC NUMBER (EINECS): 200-272-2

PERCENTAGE: 2

COMPONENT: SUCROSE

CAS NUMBER: 57-50-1

EC NUMBER (EINECS): 200-334-9

PERCENTAGE: 1

COMPONENT: BLOOD-COAGULATION FACTOR IX

CAS NUMBER: 9001-28-9

EC NUMBER (EINECS): 232-594-4

PERCENTAGE: <1

COMPONENT: L-(-) HISTIDINE

CAS NUMBER: 71-00-1

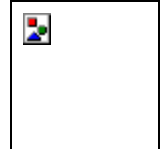
EC NUMBER (EINECS): 200-745-3

PERCENTAGE: <1

COMPONENT: POLYSORBATE 80 NF
CAS NUMBER: 9005-65-6
EC NUMBER: Not assigned.
PERCENTAGE: <1

SECTION 3 HAZARDS IDENTIFICATION

NFPA RATINGS (SCALE 0-4): HEALTH=1 FIRE=1 REACTIVITY=0



EMERGENCY OVERVIEW:

COLOR: white

PHYSICAL FORM: powder

MAJOR HEALTH HAZARDS: Accidental needle stick or puncture exposure is not expected to cause any adverse health effects.

POTENTIAL HEALTH EFFECTS:

INHALATION:

SHORT TERM EXPOSURE: no information is available

LONG TERM EXPOSURE: no information is available

SKIN CONTACT:

SHORT TERM EXPOSURE: no information is available

LONG TERM EXPOSURE: no information is available

EYE CONTACT:

SHORT TERM EXPOSURE: no information is available

LONG TERM EXPOSURE: no information is available

INGESTION:

SHORT TERM EXPOSURE: no information is available

LONG TERM EXPOSURE: no information is available

CARCINOGEN STATUS:

OSHA: No

NTP: No

IARC: No

SECTION 4 FIRST AID MEASURES

INHALATION: Remove from exposure immediately. Get medical attention.

SKIN CONTACT: Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

EYE CONTACT: Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

INGESTION: If a large amount is swallowed, get medical attention.

SECTION 5 FIRE FIGHTING MEASURES

FIRE AND EXPLOSION HAZARDS: No fire or explosion hazard is expected.

EXTINGUISHING MEDIA: regular dry chemical, carbon dioxide, water, regular foam

FIRE FIGHTING: Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

FLASH POINT: not flammable

SECTION 6 ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL RELEASE:

Collect spilled material in appropriate container for disposal. Keep unnecessary people away, isolate hazard area and deny entry.

SECTION 7 HANDLING AND STORAGE

STORAGE: Store and handle in accordance with all current regulations and standards. See original container for storage recommendations. Keep separated from incompatible substances.

HANDLING: Use methods to minimize dust.

SECTION 8 EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE LIMITS:

COAGULATION FACTOR IX (RECOMBINANT), BENEFIX(TM):

No occupational exposure limits established.

VENTILATION: Under normal conditions of use, no special ventilation equipment is needed.

EYE PROTECTION: Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

CLOTHING: Under normal conditions of use, wear suitable clothing to prevent contact with skin.

GLOVES: Wear gloves to prevent direct skin contact with any spilled material.

RESPIRATOR: No respirator is required under normal conditions of use.
Under conditions of frequent use or heavy exposure, respiratory protection may be needed.
Respiratory protection is ranked in order from minimum to maximum.
Consider warning properties before use.
Any dust and mist respirator.
Any air-purifying respirator with a high-efficiency particulate filter.
For Unknown Concentrations or Immediately Dangerous to Life or Health -
Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply.
Any self-contained breathing apparatus with a full facepiece.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: solid
COLOR: white
PHYSICAL FORM: powder
ODOR: Not available
BOILING POINT: Not applicable
MELTING POINT: Not available
VAPOR PRESSURE: Not applicable
VAPOR DENSITY: Not applicable
SPECIFIC GRAVITY: Not available
WATER SOLUBILITY: soluble
PH: Not applicable
VOLATILITY: Not applicable
ODOR THRESHOLD: Not available
EVAPORATION RATE: Not applicable
COEFFICIENT OF WATER/OIL DISTRIBUTION: Not available

SECTION 10 STABILITY AND REACTIVITY

REACTIVITY: Stable at normal temperatures and pressure.

CONDITIONS TO AVOID: Avoid contact with incompatible materials.

INCOMPATIBILITIES: oxidizing materials

HAZARDOUS DECOMPOSITION:
Thermal decomposition products: oxides of carbon

POLYMERIZATION: Will not polymerize.

SECTION 11 TOXICOLOGICAL INFORMATION

COAGULATION FACTOR IX (RECOMBINANT), BENEFIX(TM):

ADDITIONAL DATA:

Accidental needle stick or puncture exposure is not expected to cause any adverse health effects. Acute and 4-week toxicity testing in dogs, rats and mice has demonstrated no systemic toxicity at doses up to 500 ug/kg/day. Factor IX is a protein involved in coagulation and therefore has a potential to induce thrombosis. However, thrombosis has not been observed in clinical trials with rFIX, and it is likely that very high doses by a parenteral route would be required to induce thrombosis.

BLOOD-COAGULATION FACTOR IX:

TOXICITY DATA:

1000 ug/kg intraperitoneal-mouse LD50

ACUTE TOXICITY LEVEL: Insufficient Data.

ADDITIONAL DATA: The use of coagulation factor IX products has been associated with immune reactions in some patients requiring treatment.

HEALTH EFFECTS:

INHALATION:

ACUTE EXPOSURE:

BLOOD-COAGULATION FACTOR IX: No data available.

CHRONIC EXPOSURE:

BLOOD-COAGULATION FACTOR IX: No data available.

SKIN CONTACT:

ACUTE EXPOSURE:

BLOOD-COAGULATION FACTOR IX: No data available.

CHRONIC EXPOSURE:

BLOOD-COAGULATION FACTOR IX: No data available.

EYE CONTACT:

ACUTE EXPOSURE:

BLOOD-COAGULATION FACTOR IX: No data available.

CHRONIC EXPOSURE:

BLOOD-COAGULATION FACTOR IX: No data available.

INGESTION:

ACUTE EXPOSURE:

BLOOD-COAGULATION FACTOR IX: No data available.

CHRONIC EXPOSURE:

BLOOD-COAGULATION FACTOR IX: No data available.

Not available

[SECTION 13 DISPOSAL CONSIDERATIONS](#)

Dispose in accordance with all applicable regulations.

[SECTION 14 TRANSPORT INFORMATION](#)

U.S. DEPARTMENT OF TRANSPORTATION: No classification assigned.

CANADIAN TRANSPORTATION OF DANGEROUS GOODS: No classification assigned.

LAND TRANSPORT ADR/RID: No classification assigned.

AIR TRANSPORT IATA/ICAO: No classification assigned.

MARITIME TRANSPORT IMDG: No classification assigned.

[SECTION 15 REGULATORY INFORMATION](#)

U.S. REGULATIONS:

CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4): Not regulated.

SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30): Not regulated.

SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40): Not regulated.

SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):

ACUTE: No

CHRONIC: No

FIRE: No

REACTIVE: No

SUDDEN RELEASE: No

SARA TITLE III SECTION 313 (40 CFR 372.65): Not regulated.

OSHA PROCESS SAFETY (29CFR1910.119): Not regulated.

STATE REGULATIONS:

California Proposition 65: Not regulated.

CANADIAN REGULATIONS:

WHMIS CLASSIFICATION: Not determined.

EUROPEAN REGULATIONS:

EC CLASSIFICATION (CALCULATED): Not determined.

NATIONAL INVENTORY STATUS:

U.S. INVENTORY (TSCA): Exempt.

TSCA 12(b) EXPORT NOTIFICATION: Not listed.

[SECTION 16 OTHER INFORMATION](#)

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