

SAFETY DATA SHEET

Section 1: Identification

Product Name: Bio-based clot

Chemical Name/Synonyms: N/A (not a chemical product)

Hospital producing the product:

Lahey Clinic (Lahey Hospital & Medical Center), Department Neuro Interventional Radiology
41 Burlington Mall Road, Burlington, MA 01805

Company distributing the product:

Biomodex

2 rue de la Roquette, 75011 Paris, France. (www.biomodex.com)

ⓘ The bio-based clot is intended to be used in Biomodex's simulation stations only. It is not for human or animal use.

In emergency, call your local emergency services.

For information about this SDS, use this department contact: davidgray@biomodex.com

Section 2: Hazard(s) Identification

See <https://www.sigmaaldrich.com/safety-center/globally-harmonized.html> for a list of hazard classifications, signal words, hazard statements, pictograms, precautionary statements, and a description of hazards.

Hazard Classification: Classified as a biohazardous material category B

Signal Word(s): Warning

Hazard Statements: The blood clots are made of ovine blood and is a biohazardous material (category B infectious substance). A category B infectious substance is not in a form generally capable of causing permanent damage or life-threatening or fatal disease in otherwise healthy people when exposure to it occurs.

Pictograms: *No pictogram is applicable to this material*

Precautionary Statements: Personal protective equipment such as gloves should be used while handling the blood clots. Disinfection of the working area using a hospital-grade disinfectant is required after using the clot materials. Once finished, dispose the waste in a biohazard bag. Avoid contact with the skin, do not ingest.

Description of other hazards: None

Section 3: Composition/ Information on Ingredients

Chemical Name	Synonym	CAS#	Concentration
Ovine blood	N/A	N/A	Proprietary
Fibrin	N/A	N/A	Proprietary

Section 4: First-Aid Measures

General: Not expected to present a significant hazard under proper conditions of normal use

Inhalation: *Since the product is solid, it is not meant to be inhaled.* When symptoms occur go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: *None expected under normal conditions of use.* Carefully rinse with water for at least 15 minutes. Remove contact lenses, if present and easy to remove. Continue rinsing, as deemed necessary. Obtain medical attention.

Ingestion: *None expected under normal conditions of use* Rinse mouth. Do not induce vomiting. Obtain medical attention.

Chronic Symptoms: *None expected under normal conditions of use.*

If exposed or concerned of exposure, get medical advice and attention. If medical advice is needed, have product container or label at hand.

Section 5: Fire-Fighting Measures

Not applicable since it is not a chemical

Suitable extinguishing agents: N/A

Special protective equipment for firefighters: N/A

Section 6: Accidental Release Measures

Personal precautions: Safety Glasses, Gloves

Measures for environmental protection: Once finished, dispose the waste in a biohazard bag.

Measures for cleaning/collecting: Disinfection of the working area using a hospital-grade disinfectant is required after using the clot materials.

Section 7: Handling and Storage

Handling and storage: The clot model has a short shelf life. This may result in significant changes to the mechanical properties of the clot, which adversely affect clot behavior during testing and produce inaccurate data. However, any changes to the blood clot caused by incorrect handling or storage are not expected to significantly alter safety aspects. To eliminate issues derived from shipping, handling, and transport, it is our recommendation to use the clot within 1-2 days after receiving the clots. Prior to use, the clots should be stored at 4°C.

Section 8: Exposure Controls/Personal Protection

General protective and hygienic measures: Please have gloves and eye protection available.

Protection of hands: Areas to wash hands should be available for use, including mild soap and hospital-grade disinfectant.

Eye protection: Eye wash station should be available for use.

Section 9: Physical and Chemical Properties

Not applicable since it is not a chemical

Form: Plastic tube containing the blood clot (looks like a paste / jelly)

Odor: None

Odor threshold: Not applicable

pH: Not available

Melting point/melting range: Not available

Boiling point/boiling range: Not available

Flash point: Not available

Evaporation rate: Not available

Flammability: Not available

Upper/lower flammability or explosive limits: Not available

Auto ignition temperature: Not applicable

Danger of explosion: None

Vapor pressure: Not applicable
Vapor density: Not applicable
Relative density: Not applicable
Solubility in/Miscibility with water: Not available

Section 10: Stability and Reactivity

Reactivity: Hazardous reactions will not occur under normal conditions.
Chemical stability: Stable under recommended handling and storage conditions (see Section 7)
Conditions to avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.
Incompatible materials: Not known
Hazardous decomposition products: Not known

Section 11: Toxicological Information

Not applicable since it is not a chemical

Acute toxicity: Not classified.
Potential routes of exposure/potential health effects
Skin: Not classified
Eye: Not classified
Inhalation: Not classified
Ingestion: Not classified
Carcinogenic effects: Not classified
Mutagenic effects: Not classified
Reproductive toxicity: Not classified
Sensitization: Not classified
Target organs: Not classified

Section 12: Ecological Information (non-mandatory)

Ecotoxicity: Not classified
Mobility: Not available
Biodegradation: Not established
Bioaccumulation: Not established

Section 13: Disposal Considerations (non-mandatory)

Waste Disposal Recommendations: Dispose the waste in a biohazard bag
Ecology – Waste Materials: Avoid release into the environment.

Section 14: Transport Information (non-mandatory)

DOT regulations: Not regulated for transport
IMDG regulations: Not regulated for transport
IATA regulations: Not regulated for transport
TDG regulations: Not regulated for transport

Regulation for packaging: This is a category B material, it is assigned to UN3373

(<https://www.un3373.com/category-biological-substances/category-b/>)

Packaging requirements are at **packing instruction P650** (<https://www.un3373.com/un3373-packaging/p650-packaging-instruction/>)

Among the instruction for packaging you can find:

- The packaging shall consist of three components
 - a) a primary receptacle;
 - b) a secondary packaging; and
 - c) an outer packing.
- Should have Biohazard label
- Category B label used outside of the box

Section 15: Regulatory Information (non-mandatory)

Not applicable since it is not a chemical

US Federal Regulations

SARA Section 355 (extremely hazardous substances):

SARA Section 313 (specific toxic chemical listings):

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs):

TSCA (Toxic Substances Control Act):

Section 16: Other Information

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Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.