SAFETY DATA SHEET

GlaxoSmithKline

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

Material **BEXXAR (RADIO-LABELLED MONOCLONAL ANTIBODY COMPONENT)**

Synonyms IODINE I-131 TOSITUMOMAB, FORMULATED PRODUCT

Company Name GlaxoSmithKline, Corporate Environment, Health & Safety
980 Great West Road
Brentford, Middlesex TW8 9GS UK

UK General Information:	+44-20-8047-5000
Transport Emergency (EU)	+44-1865-407333
Medical Emergency	+1-612-221-3999, Ext 221
Information and Advice:	US number, available 24 hours
	Multi-language response

GlaxoSmithKline, Corporate Environment, Health & Safety
One Franklin Plaza, 200 N 16th Street
Philadelphia, PA 19102-1225 US

US General Information:	+1-888-825-5249
Transport Emergency (non EU)	+1-703-527-3887
	US number, available 24 hours
	Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
TOSITUMOMAB MONOCLONAL ANTIBODY	Unassigned	0.01 to 0.25
IODINE-131 (BOUND TO TOSITUMOMAB)	24267-56-9	Not applicable
NON-HAZARDOUS INGREDIENTS	Unassigned	99.75 to 99.99

3. HAZARDS IDENTIFICATION

Fire and Explosion This product is classified as non-flammable.

*** Health** Radioactive material.
Health effects information is based on hazards of components.
Exposure might occur via ingestion; skin; eyes.

Environment No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of radioiodine a high energy beta/gamma emitter. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	This material may cause or aggravate allergy to any hazardous components.
Health Surveillance Procedures	The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should undergo appropriate health surveillance that may include symptom enquiry, clinical examination and monitoring of lead organ effects (e.g. full blood counts). In the event of overexposure, individuals should receive post exposure health surveillance focused on the most likely health effects (e.g. full blood counts).
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. Wash down personal protective equipment with water or other suitable decontaminating material after use. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Consider radioactivity when handling any spills. Use protective clothing during clean-up prior to disposal of spilled product.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. Consult local and national regulations for reporting requirements on spills.
Decontamination Procedures	Water can be used for clean-up and decontamination operations. Avoid decontamination with acid pH solutions. All material used during clean-up should be either held for radioactive decay to background or disposed of as radioactive waste.

7. HANDLING AND STORAGE

HANDLING

General Requirements	Normal room ventilation is expected to be adequate for routine handling of this product.
Protective Systems	Minimise time of handling and operate as far as practicable from the source to reduce radiation exposure.
STORAGE	Store frozen in original lead pots.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS

Exposure Controls	Follow local regulations for monitoring and controlling exposure to radiation and radioisotopes.
*** Other Equipment or Procedures**	Routine handling of this material may require the use of radiation dosimeters. Consult local regulations or radiation safety expert. Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling. This product is listed by US NIOSH as a hazardous drug when handled in health care settings. For additional information about the NIOSH hazardous drugs programme and recommendations for preventing exposure see US NIOSH publication No. 2004-165, "Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings."

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Clarity	Clear, free of visible particles.
Colour	Colourless to slightly yellow.
Physical Form	Radioactive liquid.
Packaging	Vial in lead pot.
pH of Aqueous Solutions	7

10. STABILITY AND REACTIVITY

Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity	Not expected to be toxic following ingestion.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Irritation is not expected following direct contact with eyes.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Carcinogenicity	This is a radioactive substance. Human and animal exposure to radioactive substances has been associated with increased incidence of cancer.
Reproductive Effects	Human and animal exposure to radiation has been associated with toxicity to the developing embryo or foetus.
Other Adverse Effects	Overexposure in the workplace might have the following effects: bone marrow toxicity toxicity to rapidly dividing cells thyroid gland toxicity.

12. ECOLOGICAL INFORMATION

Summary	No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations	The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used. All product returns must be in a suitable lead pot for disposal purposes.
Regulatory Requirements	Disposal of this product must be made in accordance with applicable local, state and federal environmental regulations addressing radioactive materials

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Technical Name	BEXXAR (RADIOLABELED MONOCLONAL ANTIBODY COMPONENT)
Proper Shipping Name	Radioactive material, Type A package.
UN Number	UN 2915
Class/Division	7

International Air Transport (IATA Requirements)

Classification and Labelling	As UN Classification and Labelling above

International Maritime Transport (IMDG Requirements)

Classification and Labelling	As UN Classification and Labelling above

US Domestic Transport (DOT Requirements)

Classification and Labelling	As UN Classification and Labelling above

European Ground Transport (ADR/RID Requirements)

Classification and Labelling	As UN Classification and Labelling above

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification	Caution - radioactive materials.

Other US Regulations

TSCA Status	Exempt

16. OTHER INFORMATION

Date Approved/Revised 23-Oct-2007 **SDS Version Number** 17

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
EXPOSURE CONTROLS / PERSONAL PROTECTION	Other Equipment or Procedures
HAZARDS IDENTIFICATION	Health
IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY	

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.