SAFETY DATA SHEET

GlaxoSmithKline

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

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

Synonyms TOSITUMOMAB, FORMULATED PRODUCT

Company Name

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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

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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	1.3 to 1.5
NON-HAZARDOUS INGREDIENTS	Unassigned	98.5 to 98.7

3. HAZARDS IDENTIFICATION

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

*** Health** Handling this product in its final form presents minimal risk from occupational exposure.
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 Conditions Caused or Aggravated by Exposure	None for occupational exposure.
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. 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	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.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	Water can be used for clean-up and decontamination operations.

7. HANDLING AND STORAGE

HANDLING

General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
STORAGE	Store in a refrigerator at 2-8 °C. DO NOT FREEZE. Dispose of properly if frozen.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

*** Other Equipment or Procedures**	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 to slightly opalescent, may contain particles.
Colour	Colourless to slightly yellow.
Physical Form	Liquid.
Packaging	Vial.
pH of Aqueous Solutions	7.2

10. STABILITY AND REACTIVITY

Stability	DO NOT FREEZE - dispose of properly if frozen.
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.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

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.
Regulatory Requirements	Observe all local and national regulations when disposing of this material.

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

Transport Information	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

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 This product is not classified as hazardous according to the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

Date Approved/Revised 25-Oct-2007 **SDS Version Number** 15

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.