

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier:

Product Name: Anti-Human CD20 mAb

Product Numbers: GMP-TL502

1.2 Relevant identified uses of the substance or mixture and uses advised against:

Relevant identified uses: Ideal antigen for treating B lymphocyte related diseases.

Not for any animal, human or therapeutic use.

Uses advice against: No additional information available

1.3 Details of the supplier of the Safety Data Sheet:

Beijing T&L Biological Technology Co.Ltd.

Floor 1-3, Building 13, No. 50, Huatuo Road, Daxing District, Beijing, 102629, China

Tel: +86-10-53656596

Fax: +86-10-68640843

E-mail: service@seafrom.cn

website: <http://www.seafrom.com/>

1.4 Emergency telephone number:

Emergency number: +86-10-53656596

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) 1272/2008, the product is not classified as hazardous

2.2 Label elements:

Label elements according to Regulation (EC) 1272/2008, the product does not need to be labelled

2.3 Other hazards:

Not /hazardous

CAUTION!

Handle as if capable of transmitting infectious agents. When handling, follow appropriate guidelines in accordance with good laboratory hygiene and safety protocols. Appropriate clothing should be worn to limit exposure to eyes, skin, and mucous membranes. Wash hands after use.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances: Organic compound (Human-derived material)

Composition: Mannitol, PBS, anti human CD20 monoclonal antibody.

Product Description: CD20 is a specific marker molecule on the surface of B lymphocytes, expressed on over 95% of normal or malignant B lymphocytes, and has no expression of CD20 antigen in hematopoietic stem cells, progenitor cells, and other normal tissues. It is composed of 297 amino acids with a molecular weight of 33kD. 34-36 kD belongs to non glycosylated phosphoproteins, and its antigenic epitope is a 43 amino acid ring region in the third and fourth transmembrane intervals. CD20 does not undergo significant internalization or cell surface detachment after binding to antibodies, making it an ideal antigen for treating B lymphocyte related diseases. Due to the fact that primitive normal B cells are not affected by anti CD20 monoclonal antibodies, they can still reconstruct the B cell population even after killing most lymphoma cells and normal B cells that express CD20 molecules. Therefore, anti CD20 monoclonal antibodies are increasingly being used in the treatment of B cell related diseases.

CAS Number: None

EC Number: None

Annex I Index Number: None

3.2 Mixtures:

Information not required

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

General Information: Consult a doctor in case of discomfort with this Security Data Sheet.

Skin Contact: Rinse with soap and plenty of water after each contact.
If symptoms arise, consult a physician.

Eye Contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. If symptoms occur, consult a physician.

Ingestion: Never give anything by mouth to an unconscious person.
Wash out mouth with water. Do not induce vomiting without medical advice. If swallowed consult a physician.

Inhalation: Move to fresh air. If symptoms persist, consult a physician.
If not breathing, give artificial respiration.

4.2 Most important symptoms and effects, both acute and delayed:

Acute and delayed effects are indicated in section 11.

4.3 Indication of any immediate medical attention and special treatment needed:

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable Extinguishing Media: use extinguishing media appropriate for surrounding fire.

5.2 Special hazards arising from the substance or mixture:

Fire hazard: Not flammable.

Explosion hazard: Product is not explosive.

Reactivity: Stable at ambient temperature and under normal conditions of use.

5.3 Advice for fire fighters:

Precautionary measures fire: Exercise caution when fighting any chemical fire.

Firefighting instructions: Use water spray or fog for cooling exposed containers.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel: Use personal protective equipment. Avoid contact with eyes and skin.

For emergency responders: Use personal protective equipment. Avoid contact with eyes and skin.

6.2 Environmental precautions:

This product is not classified as dangerous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up:

Methods and material for containment: Soak up with inert absorbent material.

After clean-up, disinfect affected area.

Deposit in appropriate containers for removal and disposal.

Methods and material for cleaning up: Soak up with inert absorbent material.

After clean-up, disinfect affected area.

Deposit in appropriate containers for removal and disposal.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

Recommendations shall be specified to:

Avoid contact with skin, eyes and clothing.

Wear personal protective equipment.

Keep away from heat. Keep away from sources of ignition.

Ground all equipment containing material.

Advice on general occupational hygiene shall be provided:

Avoid contact with skin, eyes and clothing.

Wear personal protective equipment.

Ground all equipment containing material.

Remove contaminated, saturated clothing immediately.

Do not eat, drink or smoke when using this product.

7.2 Conditions for safe storage, including any incompatibilities:

Storage conditions: Keep container tightly closed. Keep container in a dry, cool, Well-ventilated area.

Store in the dark at (2-8) °C.

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special

recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment.

There are no environmental limits for the substances contained in the product.

8.2 Exposure controls: None

Appropriate engineering controls: In particular, ensure adequate ventilation when using in confined areas, or use in fume hoods when permitted. Ensure that all engineering measures described in SDS section 7 are in place and that the laboratory is equipped with a safety shower and eyewash table.

Information on System Design: None

Personal Protective Equipment:

Respiratory Protection: If the risk assessment indicates that it is necessary, use a suitable respirator.

Hand Protection: Use protective gloves.

Eye Protection: Select appropriate goggles.

Skin Protection: Use appropriate chemical resistant gloves (the minimum requirement is BS EN 374:2003). Wash and dry hands before use, and check the integrity of gloves.

Body Protection: wear appropriate protective clothing.

Thermal hazards: None.

Environmental exposure controls: None.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

Appearance: Liquid

Odour: Non-applicable

Odour threshold: Non-applicable

pH: 6.5-7.5

Melting point: Non-applicable

Initial boiling point: Non-applicable

Boiling range: Non-applicable

Flash point: Non-applicable

Evaporation rate: Non-applicable

Flammability (solid, gas): Non-applicable

Upper flammability limits: Non-applicable

Lower flammability limits: Non-applicable

Vapour pressure: Non-applicable

Vapour density: Non-applicable

Relative density: Non-applicable

Solubility: Soluble

Auto-ignition temperature: Non-applicable
Decomposition temperature: Non-applicable
Viscosity: Non-applicable
Explosive properties: Non-applicable
Oxidising properties: Non-applicable

9.2 Other information:

Thermal decomposition: Non-applicable
Vapour density: Non-applicable
Evaporation rate: Non-applicable
Surface tension at 20°C: Non-applicable
Refraction index: Non-applicable

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity: Stable under recommended transportation or storage conditions.

10.2 Chemical stability: Stable under recommended storage conditions.

10.3 Possibility of hazardous reaction: None

10.4 Conditions to avoid: No dangerous reaction known under conditions of normal use.

10.5 Incompatible materials: Strong acid / base, strong oxidizing / reducing agent.

10.6 Hazardous decomposition: Strong acid / base, strong oxidizing / reducing agent.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

Mixtures

Acute toxicity:

Skin corrosion/irritation: May cause skin irritation in susceptible person

Serious eye damage/irritation: May cause eye irritation in susceptible person

Respiratory tract or skin sensitization: may cause respiratory tract or skin allergy to allergic people

Inhalation: The throat may be irritated and the chest feels tight

Ingestion: May irritate throat

Subacute/Chronic toxicity:

Carcinogenicity: Not classified

Mutagenicity: Not classified

Teratogenicity: Not classified

Narcotic effects: Not classified

Reproductive effects: Not classified

Developmental effects: Not classified

Ingredients:

Acute toxicity: Not classified

Subacute/Chronic toxicity: Not classified

Other adverse effects: Toxicological properties have not been thoroughly investigated.

Target organ effects: No known effects under normal use conditions

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity: No information available

12.2 Persistence and degradability: The product is biodegradable.

12.3 Bioaccumulative potential: Does not bioaccumulate.

12.4 Mobility in soil: Does not bioaccumulate.

12.5 Results of PBT and vPvB assessment:

Persistent, bioaccumulative and toxic substances (PBT-substances):None.

Very persistent and very bioaccumulative substances (vPvB-substances):None.

12.6 Other adverse effects: None.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods: Dispose of in accordance with local, regional, national, provincial, territorial and international regulations.

Product:

Transfer to a suitable container and arrange for collection by a specialized disposal company according to relevant regulations.

Contaminated packaging:

Dispose of hazardous or toxic waste in regulated landfills or other methods according to relevant regulations.

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA

14.1 UN number: Not classified as dangerous in the meaning of transport regulations

14.2 UN proper shipping name: Not classified as dangerous in the meaning of transport regulations

14.3 Transport hazard class(es): Not classified as dangerous in the meaning of transport regulations

14.4 Packing group: Non-applicable

14.5 Environmental hazards: Non-applicable

14.6 Special precautions for user: Non-applicable

14.7 Transport in bulk according to AnnexII of MARPOL73/78 and the IBC Code:Non-applicable

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

No known hazards.

No REACH Annex XVII restrictions.

Contains no REACH candidate substance.

15.2 Chemical safety assessment: No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Research Use Only (RUO). Not for any animal, human or therapeutic use. The above information is believed to be correct to the best of our knowledge but does not purport to be all-inclusive and shall be used only as a guide. It does not represent any guarantee of the properties of the product. All materials and mixtures may present unknown hazards and should be used with caution. Beijing T&L Biological Technology Co.,Ltd. shall not be held liable for any direct, indirect, consequential or incidental damages resulting from handling or from contact with the above product.