

MATERIAL SAFETY DATA SHEET

Version: 1.0

Effective Date: Since Dec 08, 2015

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As required by OSHA 29 CFR 1910.1200, (EC) N. o 1907/2006, (EC) N. o 1272/2008

Section 1: Product and Company Identification	
Product Name	SB2
Product Number	Common
Intended Use	Pharmaceutical drug substance
Company	Samsung Bioepis 107, Cheomdan-daero, Yeonsu-gu, Incheon, Republic of Korea
Emergency Phone	+82-32-455-6119

Section 2: Hazards Identification	
Hazard Class / Category	no classification and labelling according to GHS
Hazard Symbol	Not Applicable
Hazard Warning	Not Applicable
Hazard Statements	Not Applicable
Precautionary Statements	Not Applicable
Other Hazard Information	
CAUTION! This is an active pharmaceutical ingredient or intermediate for research only. The hazards of this compound have not been fully investigated. Use care when handling this material, avoid all contact.	

Section 3: Composition / Information on Ingredients		
Chemical Name	Infliximab	
Chemical Formula	Infliximab is a monoclonal antibody that acts as an antagonist of tumor necrosis factor alpha	
Ingredient*	CAS #	Concentration
Infliximab	170277-31-3	20 mg/mL
Monobasic sodium phosphate monohydrate	10049-21-5	1.11 mg/mL
Dibasic sodium phosphate heptahydrate	7782-85-6	0.52 mg/mL
Sucrose	57-50-1	100 mg/mL
Polysorbate 80	9005-65-6	0.1 mg/mL

Section 4: First Aid Measures

Eye Contact:

Remove from source of exposure. Flush with copious amount of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact:

Remove from source of exposure. Flush with copious amount of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation:

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion:

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders:

Use personal protective equipment.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media

Use water spray, foam, dry chemical or carbon dioxide

Unsuitable Extinguishing Media / Unusual Risks

Do not use water jet.

Special Fire-Fighting Equipment for Fire-Fighters

In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

Section 6: Accidental Release Measures

Personal Precautions and Protection

Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions

Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

Clean Up Procedures(In case of spill)

Remove spilled products thoroughly with absorbent paper and then again wipe contaminated area by using 70% ethanol. Avoid formation of dust and aerosols.

The material used for cleaning must be disposed by local regulations related to waste disposal.

Section 7: Storage and Handling**Handling**

For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage

No special safety precautions required. Keep container tightly closed.

Section 8: Exposure Controls / Personal Protection

The physical, chemical and occupational toxicological properties of this material have not been thoroughly investigated. Use caution when handling and avoid exposure. A comprehensive risk assessment for a particular operation should be performed to determine appropriate exposure controls.

Respiratory protection

Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure.

Respiratory protection should not substitute for feasible engineering controls.

- respiratory protection not necessary during normal operations
- breathing apparatus in case of aerosol mist formation

Hand protection

Protective gloves(eg made of neoprene, nitrile or butyl rubber)

Eye protection

Safety Glasses

Section 9: Physical and Chemical Properties

Molecular weight:145,880 daltons(without carbohydrate)

pH: 6.3

Physical form: Frozen Liquid

Order: None

Appearance/Color: Clear

Section 10: Stability and Reactivity**Stability**

Stable at room temperature.

Incompatible materials / conditions

No data available

Hazardous decomposition products

None under normal use.

Hazardous polymerization

None under normal use.

Section 11: Toxicological Information

Acute Toxicity

Not applicable (Not conducted)

Signs and Symptoms of Exposure

Not applicable (Not conducted)

Effects by inhalation, dermal contact, ingestion or eye contact

Not applicable (Not conducted)

Sensitization

Not applicable (Not conducted)

Subchronic toxicity

Not applicable (Not conducted)

Chronic Toxicity

Not applicable (Not conducted)

Carcinogenicity

Not applicable (Not conducted)

Genotoxicity

Not applicable (Not conducted)

Reproductive Toxicity

Not applicable (Not conducted)

Teratogenicity

Not applicable (Not conducted)

Target Organs

Not applicable (Not defined)

Section 12: Ecological Information

The following effects are based on the Active Pharmaceutical Ingredient.

Ecotoxicity

No appreciable ecotoxic potential is to be expected

*** Mobility in soil**

Not available

Chemical Fate Information

This product is protein based and will rapidly degrade in the environment.

Section 13: Disposal Considerations**Product/Packaging Disposal**

Dispose of in accordance with local and national regulations regarding waste disposal.

Section 14: Transport Information

This material is not classified as hazardous for transport.

Not regulated by US DOT or IATA

Section 15: Regulatory Information

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

Chemical Safety Assessment

No CSA has been conducted.

Section 16: Other Information

Other Special Considerations: Not available.

The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, SAMSUNG BIOEPIS will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.