

MATERIAL SAFETY DATA SHEET

Approved

Version: 5.0

Effective Date: Since Jan 10, 2018

Revision Date: Apr 06, 2023

As required by Korean Industrial Safety and Health Act Section 110

Section 1. Product and Company Identification	
Product Name	SB17
Product Number	Common
Intended Use	Pharmaceutical drug product
Company	SAMSUNG BIOEPIS Co., Ltd. 76, Songdogoyoyuk-ro, Yeonsu-gu, Incheon, Republic of Korea
Emergency Phone	+82-32-728-0119

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! Use care when handling this material	

Section 3. Composition / Information on Ingredients		
Chemical Name	Not Applicable	
Chemical Formula	Not Applicable	
Ingredient	CAS #	Concentration
Ustekinumab	815610-63-0	Confidential
L-Histidine	71-00-1	Confidential
L-Histidine Hydrochloride monohydrate	5934-29-2	Confidential
Sucrose	57-50-1	Confidential
Polysorbate 80	9005-65-6	Confidential
Water for Injection	7789-20-0	Confidential

Section 4. First Aid Measures
In case of eye contact Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention immediately.
In case of skin contact In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Cover the irritated skin with an emollient. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.
If inhaled If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.
If swallowed If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

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

To maintain product quality, do not store in heat or direct sun-light.

Store in original container. Recommended storage temperature: 2°C - 8°C

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.

Ingredient	CAS #	OEL (Occupational Exposure Limit)	Legal ground
Ustekinumab	815610-63-0	Not applicable	Korean Industrial Safety and Health Act Section 106
L-Histidine	71-00-1	Not applicable	
L-Histidine Hydrochloride monohydrate	5934-29-2	Not applicable	
Sucrose	57-50-1	*TWA 10mg/m ³	
Polysorbate 80	9005-65-6	Not applicable	
Water for Injection	7789-20-0	Not applicable	

*TWA : Time Weighted Average

Exposure Route

350 mcg/m³

Engineering Controls

Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.

Respiratory Protection

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Base respirator selection on a risk assessment. Hand protection Protective gloves (e.g. made of neoprene, nitrile or butyl rubber) Eye protection Safety Glasses Body protection Body protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Body protection should not substitute for feasible engineering controls. - Body protection not necessary during normal operations Other PPE Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.
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Section 9. Physical and Chemical Properties Caution! The physical, chemical and occupational toxicological properties of this material have not been thoroughly investigated. Use caution when handling and avoid exposure. Appearance: Clear to slightly opalescent, colorless to light yellow liquid Odor: None pH: approximately 6.0 Specific gravity: Not available Solubility (water): Not available Evaporation rate: Not available Partition coefficient: Not available Vapor Pressure: Not available Boiling Point: Not available Melting Point: Not available Physical Form: Liquid

Section 10. Stability and Reactivity Stability Stable at 2-8°C storage condition Incompatible materials / conditions No data available Hazardous decomposition products None under normal use. Hazardous polymerization None under normal use.
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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

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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

Not available

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 Disposal**

Dispose of in accordance with local and national regulations.

Packaging Disposal

Dispose of in accordance with local and national regulations.

Other regulatory information

Dispose of in accordance with local and national regulations.

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 Korean Industrial Safety and Health Act Section 110

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. 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

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