Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **SILIQ™ (brodalumab)**

Product Code • 301870004021; NDC 0187-0004-02

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

Recommended use • SILIQ™ is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals Luxembourg S.à.r.l.
Grand Duchy of Luxembourg, L-1931

Luxembourg

Telephone (General) • 1-800-321-4567

Supplier • Valeant Pharmaceuticals North America, LLC
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Supplier • 1-800-535-5053 - US - Infotrac

Supplier • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

United States (US)

According to: OSHA 29 CFR 1910.1200 HCS

Classification of the substance or mixture

OSHA HCS 2012 • Classification criteria not met

Label elements

OSHA HCS 2012

Other hazards

OSHA HCS 2012 • No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition		
Chemical Name	**Identifiers**	**%**
Brodalumab	**CAS:**1174395-19-7	14%
Proline, L-	**CAS:**147-85-3	< 2.5%
Polysorbate 20	**CAS:**9005-64-5	< 0.1%
Glutamic acid, L-	**CAS:**56-86-0	< 0.5%
Water	**CAS:**7732-18-5	Balance

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation
- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin
- After contact with skin, take off immediately all contaminated clothing and wash immediately with plenty of (to be specified by manufacturer). If irritation develops and persists, get medical attention.

Eye
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion
- If swallowed, seek medical advice immediately and show this container or label.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media
- Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media
- No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards
- None known - product is not flammable or combustible.

Hazardous Combustion Products
- No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8.

Emergency Procedures
- No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

Methods and material for containment and cleaning up

Containment/Clean-up Measures
- Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Section 7 - Handling and Storage

Precautions for safe handling

Handling
- No special handling is required. Refer to Section 8. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage
- Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light and physical damage during storage. When necessary, prefilled syringes can be stored at room temperature up to a maximum of 77°F (25°C) in the original carton for a maximum single period of 14 days with protection from light and sources of heat. Once the prefilled syringe has reached room temperature, do not place back into the refrigerator. Discard after 14 days at room temperature. DO NOT FREEZE. DO NOT SHAKE.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines
- No regulatory limits have been established. Good industrial hygiene practices should be followed to reduce exposures as much as possible.

Exposure controls

Engineering Measures/Controls
- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory
- No special controls or personal protection required under conditions of intended use.

In the event of a bulk spill, a NIOSH-certified air-purifying respirator with organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face
- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.

Hands
- Wear protective gloves when handling bulk product before closed in final packaging.

Skin/Body
- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Environmental Exposure Controls
- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	SILIQ is a clear to slightly opalescent, colorless to slightly yellow solution and may contain a few translucent to white, amorphous particles .
Color	Colorless to slightly yellow.	Odor	No odor.
Odor Threshold	No data available		
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	4.8
Specific Gravity/Relative Density	No data available	Water Solubility	No data available
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity
- No dangerous reactions known.

Chemical stability
- Stable under normal temperatures and pressures.

Possibility of hazardous reactions
- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information

- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

GHS Properties	Classification
Acute toxicity	**OSHA HCS 2012** • Classification criteria not met
Skin corrosion/Irritation	**OSHA HCS 2012** • Classification criteria not met
Serious eye damage/Irritation	**OSHA HCS 2012** • Classification criteria not met
Skin sensitization	**OSHA HCS 2012** • Classification criteria not met
Respiratory sensitization	**OSHA HCS 2012** • Classification criteria not met
Aspiration Hazard	**OSHA HCS 2012** • Classification criteria not met
Carcinogenicity	**OSHA HCS 2012** • Classification criteria not met
Germ Cell Mutagenicity	**OSHA HCS 2012** • Classification criteria not met
Toxicity for Reproduction	**OSHA HCS 2012** • Classification criteria not met
STOT-SE	**OSHA HCS 2012** • Classification criteria not met
STOT-RE	**OSHA HCS 2012** • Classification criteria not met

Potential Health Effects

Inhalation

Acute (Immediate)

- No data available.

Chronic (Delayed)

- No data available.

Skin

Acute (Immediate)

- No data available.

Chronic (Delayed)

- No data available.

Eye

Acute (Immediate)

- No data available.

Chronic (Delayed)

- No data available.

Ingestion

Acute (Immediate)

- No data available.

Chronic (Delayed)

- No data available.

Other

Acute (Immediate)

- No data available.

Chronic (Delayed)

- No data available.

Reproductive Effects

- A combined embryofetal development and pre- and post-natal development study was conducted in cynomolgus monkeys administered brodalumab. No brodalumab-related effects on embryofetal toxicity or malformations, or on morphological, functional or

immunological development were observed in infants from pregnant monkeys administered weekly subcutaneous doses of brodalumab up to 26 times the MRHD from the beginning of organogenesis to parturition (on a mg/kg basis of 90 mg/kg/week). There are no human data on SILIQ use in pregnant women to inform a drug associated risk. Human IgG antibodies are known to cross the placental barrier; therefore, SILIQ may be transmitted from the mother to the developing fetus. In a combined embryofetal development and pre- and post-natal development study, no adverse developmental effects were observed in infants born to pregnant monkeys after subcutaneous administration of brodalumab during organogenesis through parturition at doses up to 26 times the maximum recommended human dose (MRHD).

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste
- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user
- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
- No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications • No data available

Inventory					
Component	**CAS**	**Canada DSL**	**Canada NDSL**	**EU EINECS**	**TSCA**
Brodalumab	1174395-19-7	No	No	No	No
Glutamic acid, L-	56-86-0	Yes	No	Yes	Yes
Polysorbate 20	9005-64-5	Yes	No	No	Yes
Proline, L-	147-85-3	Yes	No	Yes	Yes

Canada

Labor

Canada - WHMIS 1988 - Classifications of Substances

• Polysorbate 20	9005-64-5	Uncontrolled product according to WHMIS classification criteria
• Glutamic acid, L-	56-86-0	Uncontrolled product according to WHMIS classification criteria
• Proline, L-	147-85-3	Uncontrolled product according to WHMIS classification criteria
• Brodalumab	1174395-19-7	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Polysorbate 20	9005-64-5	Not Listed
• Glutamic acid, L-	56-86-0	Not Listed
• Proline, L-	147-85-3	Not Listed
• Brodalumab	1174395-19-7	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Polysorbate 20	9005-64-5	Not Listed
• Glutamic acid, L-	56-86-0	Not Listed
• Proline, L-	147-85-3	Not Listed
• Brodalumab	1174395-19-7	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Polysorbate 20	9005-64-5	Not Listed
• Glutamic acid, L-	56-86-0	Not Listed
• Proline, L-	147-85-3	Not Listed
• Brodalumab	1174395-19-7	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Polysorbate 20	9005-64-5	Not Listed
• Glutamic acid, L-	56-86-0	Not Listed
• Proline, L-	147-85-3	Not Listed
• Brodalumab	1174395-19-7	Not Listed

Section 16 - Other Information

Revision Date	• 14/March/2017
Last Revision Date	• 23/February/2017
Preparation Date	• 23/February/2017
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