

Safety Data Sheet



Bristol-Myers Squibb Company

1. IDENTIFICATION			
<i>Product Information</i>			
Product name	EMPLICITI (elotuzumab) for injection		
Version	3.1, 29.11.2016		
Jurisdiction	This Safety Data Sheet was prepared in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for the United States of America (USA) (CFR 1910.1200), European Union (EU) (EC 1272/2008) and United Nations (UN). The following countries utilize the UN GHS classification process: Mexico, Brazil, China, New Zealand, Canada, Japan, and Korea.		
Synonyms	Empliciti (elotuzumab)300 mg/vial and 400 mg/vial, Elotuzumab Lyophilized powder for Injection, 300 mg/vial and 400 mg/vial; BMS-901608-01; HuLuc63		
Other information	Project Name: 061E6, 01102		
Intended Uses	This material is a finished drug product for patient use. It is used in the treatment of cancer. It is a protein.		
<i>Company/Undertaking Identification</i>			
Address	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <u>USA</u> Bristol-Myers Squibb Company P.O. Box 191 New Brunswick, New Jersey 08903 United States of America 1-800-332-2056 </td> <td style="width: 50%; vertical-align: top;"> <u>Ireland</u> Bristol-Myers Squibb Company Swords Laboratories, Watery Lane Swords, Ireland MG-GBS-MSDS-Request@bms.com 353-1813-9456 </td> </tr> </table>	<u>USA</u> Bristol-Myers Squibb Company P.O. Box 191 New Brunswick, New Jersey 08903 United States of America 1-800-332-2056	<u>Ireland</u> Bristol-Myers Squibb Company Swords Laboratories, Watery Lane Swords, Ireland MG-GBS-MSDS-Request@bms.com 353-1813-9456
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Emergency Phone No.	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%;"> USA (also Canada, Puerto Rico and the Virgin Island): 1-800-424-9300 Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC. </td> <td style="width: 50%;"> <u>Ireland</u>: 353-1813-9456 </td> </tr> </table>	USA (also Canada, Puerto Rico and the Virgin Island): 1-800-424-9300 Other Countries: See "Section 16" for country-specific emergency phone numbers from CHEMTREC.	<u>Ireland</u> : 353-1813-9456
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2. HAZARDS IDENTIFICATION	
Classification and Labelling Common to All Jurisdictions	
Classification	Not Rated Substance not fully tested.
Precautionary Statements	Wash hands after handling to minimize exposure. Handle as a potentially hazardous material. Avoid ingestion, inhalation, skin and eye contact.
Other information	99.7% of the mixture consists of ingredients(s) of unknown hazards to the aquatic environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS					
Components	Concentration	CAS No.	EU only		Other Registration No.
			EC No./REACH Registration No.	H-code(s)	

<i>Hazardous components</i>					
Elotuzumab	39 %	Trade Secret	--	--	--
Sucrose	< 60 %	57-50-1	200-334-9	--	--
<i>Other ingredients</i>					
Non-Hazardous Ingredients	< 5 %	Not available	--	--	--
See section 16 for H-code text.					

4. FIRST AID MEASURES

Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. Discard contaminated clothing or wash before re-use.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.
Ingestion	Do NOT induce vomiting. Consult a physician if necessary. Never give anything by mouth to an unconscious person.
Notes to Physician	Material not fully tested. Refer to Section 11.
Medical Surveillance	Employees who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Nonflammable
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Not available Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides (COx), nitrogen oxides (NOx)
Other information	Decontaminate protective clothing and equipment before reuse.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Wet down any dust to prevent generation of aerosols, if appropriate. Cover with suitable material.
Cleanup Methods	Spill prevention procedures and a spill response procedure should be implemented. Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up. Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

7. HANDLING AND STORAGE	
Handling Precautions	Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Container Requirements	Store in the original primary packaging as provided.
Storage Conditions	Store at 2 - 8°C. Protect against light. Do not freeze or shake. Keep away from heat, sparks and flames.
Specific use(s)	Refer to Section 1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION				
Exposure limit(s)	Company Guideline	ACGIH	Germany OEL	UK MEL
Elotuzumab	10 µg/m3 STEL 3 µg/m3 TWA	--	--	--
Sucrose		10 mg/m3 TWA	--	--
Sucrose	Occupational Exposure Limits have been established by: - Belgium - Estonia - Spain - France - Ireland - The Netherlands - Portugal			
Recommended Industrial Hygiene Monitoring Methods	Contact the Bristol-Myers Squibb AIHA accredited Industrial Hygiene Laboratory at (USA) 732-227-6338. General - The health hazard risk of handling this material is dependent on many factors, including physical form, % API in material being handled, duration and frequency of process task, and effectiveness of controls. If it is necessary to handle this compound outside of engineering controls, an exposure risk assessment should be conducted and procedures documented by a qualified EHS professional.			
EXPOSURE CONTROLS / PERSONAL PROTECTION FOR MATERIAL AS SUPPLIED				
This formulation contains an active pharmaceutical ingredient (API) with the guideline limit noted above. To keep the API below the recommended guideline, the material as supplied should be controlled during handling to limit total airborne aerosol exposure to: 4,875 µg/m ³ (For internal BMS use: Biological Control Category A ≥ 1 µg/m ³).				

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls and Ventilation	<p>LABORATORIES: General laboratory dilution ventilation is acceptable for open handling of low energy small scale processes. Low energy processes (e.g. spatula transfers, weighing, low velocity stirring, physical examination) should use protective shielding to limit the spread of dust or aerosol spread.</p> <p>When handling larger quantities, during operations that may exceed the recommended exposure control limits or high energy processes (e.g. fluid bed drying, milling, sonication, homogenization, pressurized venting, pressurized transfers, blending, high energy mixing) operations should be performed using standard laboratory controls such as a fume hood, biological safety cabinet (Class II, Type A2 with thimble connection, B1, or B2); glove box; approved vented enclosure, and/or closed or contained systems.</p> <p>MANUFACTURING: Perform closed transfers when feasible. Avoid generation of dust. Control total dust levels to recommended control limits for material as supplied (based on concentration of API in material being handled). Establish a spill/leak procedure as outlined in Section 6 to address equipment failures/leaks. Exposures are typically controlled by GMP design specifications under normal operations.</p> <p>CLINICAL: When preparing drug in a clinical setting, use good clinical practice for drug preparation. If the potential for personal exposure exists, use an approved vented enclosure such as a fume hood or biological safety cabinet if available. Please refer to the general guidance at the beginning of this section.</p>
Respiratory protection	Use and selection of respiratory protection is based upon an exposure risk assessment and potential for aerosol generation. When engineering controls are not sufficient to control exposure, wear an approved respiratory protection device that is adequate to control exposure based on measured or estimated airborne, and the rating for the device. Follow local regulatory requirements.
Eye protection	Wear safety glasses with side-shields. Face shields or chemical safety goggles may be required if contact potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.
Hand protection	When handling solutions wear impermeable gloves (e.g. latex or nitrile). Persons who are allergic to natural rubber latex should select gloves made from one of the other materials.
Skin and body protection	<p>LABORATORIES: Wear laboratory coat. Wear disposable shoe covers as appropriate.</p> <p>MANUFACTURING: Wear laboratory coat or full coverall of low permeability. Wear wrist gauntlets/sleeves and shoe covers as appropriate.</p> <p>CLINICAL: When preparing drug in clinical setting wear lab coat.</p>
Hygiene	Wash hands and face before breaks and immediately after handling the product.
Environmental exposure controls	Prevent release to drains and waterways.

9. PHYSICAL AND CHEMICAL PROPERTIES*General Information**Appearance*

Physical State
Color

solid
white to off-white

9. PHYSICAL AND CHEMICAL PROPERTIES

Form	lyophilized cake
<i>Odour</i>	
Odour	Not available
Odor Threshold	Not available
pH	6 (as aqueous solution)
<i>Other information</i>	
Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coefficient [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	soluble
Specific Gravity/ Relative density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available
<i>Thermal/Stability properties</i>	
Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available
Flammability	Nonflammable
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	Not available
<i>Vapor Properties</i>	
Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY

<i>Stability</i>	
Chemical Stability	Stable under recommended storage conditions.
Conditions to avoid	Not available
Materials to avoid	Not available

10. STABILITY AND REACTIVITY

Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides (CO _x), nitrogen oxides (NO _x)
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Hazardous reactions	None known.
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Sensitivity to static discharge/Dust exp.

Summary Statements	Although material has not been specifically tested, fine dust suspended in air in sufficient concentration and in the presence of an ignition source may pose a potential explosion hazard. Provide appropriate bonding and grounding protection to control static charge. Powder handling equipment such as dust collectors, dryers, and mills may require additional protective measures (e.g. explosion venting, inerting, etc.).
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11. TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion: May cause damage to organs through prolonged or repeated exposure. inhalation: Proteins may cause allergic reactions in some individuals.
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Eye Irritation	<u>Sucrose</u> Dust may cause mechanical irritation.
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Skin Irritation	<u>Sucrose</u> Dust may cause mechanical irritation.
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Respiratory Irritation	<u>Elotuzumab</u> Possible respiratory sensitizer <u>Sucrose</u> Dust may cause mechanical irritation.
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Sensitization	Not available
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Acute Toxicity Study	Acute Oral <u>Sucrose</u> LD50 (rat): 29,700 mg/kg Acute toxicity (other routes of administration) <u>Elotuzumab</u> LD50 (monkey, intravenous): > 100 mg/kg No mortality occurred. <u>Sucrose</u> LD50 (mouse, intraperitoneal): 14,000 mg/kg
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Repeated Dose Toxicity	Not available
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Genetic Toxicity	<u>Sucrose</u> Mutagenicity Assessment
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11. TOXICOLOGICAL INFORMATION			
Not classified as mutagen according to GHS criteria.			
Carcinogenicity	<u>Sucrose</u> Carcinogenicity Assessment Not classifiable as to its carcinogenicity to humans.		
Carcinogenicity	ACGIH	IARC	NTP
Elotuzumab	--	--	--
Sucrose	A4	--	--
Reproductive Toxicity	<u>Sucrose</u> 4 Days oral (daily) Reproductive and developmental study (rat) No effects were observed		
Developmental Toxicity	<u>Sucrose</u> Developmental Toxicity Assessment Fetal malformations were observed after very high doses in animal studies.		
Human experience	Experiences with Human Exposure <u>Elotuzumab</u> Intravenous injection Clinical trials – Monotherapy 8 weeks low exposure - acute effects include: chills, fever, cough, nausea, vomiting, fatigue, insomnia, skin flushing, hypotension, headache, muscle effects, dizziness, rash, kidney toxicity, inflammation of gastrointestinal tract, diarrhea, constipation, abdominal pain, chest pain, change in heart rate, infusion reaction, breathing difficulties, hypersensitivity, decreased white blood cell count, anemia, infection, measurable drug-specific antibodies, death. <u>Sucrose</u> General effects low exposure - acute effects include: cavities. low exposure - long term exposure effects include: skin disorders.		
Target Organs	<u>Elotuzumab</u> immune system		
Symptoms	<u>Elotuzumab</u> See "Human Experience". <u>Sucrose</u> See "Human Experience".		
Pharmacokinetics/	<u>Elotuzumab</u>		

11. TOXICOLOGICAL INFORMATION

Toxicokinetics	Absorption: Proteins greater than 10 kilodaltons (kDa) are not expected to exhibit systemic bioavailability of greater than 1% by the inhalation route. Distribution: Data available upon request. Metabolism: Data available upon request. Elimination: Half-life = 99 - 186 Hour(s) (Human).
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Other Toxicity Information	Not available
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Other Information:	The toxicological information provided in this SDS may not be applicable to occupational routes of exposure. Therefore, this substance is not classified according to GHS criteria.
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12. ECOLOGICAL INFORMATION

Ecotoxicity effects	Not available
Mobility	Not available
Persistence and degradability	Not available
PBT and vPvB assessment	Not available

13. DISPOSAL CONSIDERATIONS

Advice On Disposal And Packaging	Dispose of contents/container in accordance with local regulation. Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.
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Other information	Disposal by incineration is recommended.
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14. TRANSPORT INFORMATION

This material is not a dangerous good for the purpose of transportation in all modes.	
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15. REGULATORY INFORMATION**United States of America**

313 Toxic Release Inventory	No components listed on the SARA 313 inventory.
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TSCA Inventory	Not listed. Food, drug and cosmetic products are exempt from TSCA.
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EU Regulation (EC) No 1272/2008)DRUG PRODUCT

Classification	Medicinal products are exempt from classification and labeling requirements under EU Regulation (EC) No 1272/2008.
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Regulatory Authorizations and Restrictions:	Not available
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16. OTHER INFORMATION

Text of H-code(s) mentioned in Section 3.	
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Not available		
<i>Recommended Restrictions for Use:</i>		
Not available		
<i>SDS preparation information</i>		
Prepared by	Global Environment, Health, Safety, and Sustainability 1-732-227-7380	
Prepared on	29.11.2016 DD/MM/YYYY	
This data sheet contains changes from the previous version in section(s): 1, 3, 4, 5, 9, 11, 15, and 16.		
<i>Other information</i>		
HMIS	Health	0*
	Flammability	0
	Reactivity	Not Determined (ND)
	Personal protective equipment	See Section 8.
NFPA	Health	0
	Fire	0
	Reactivity	ND
	Special	ND
	<p>The diagram is a diamond shape divided into four quadrants. The top quadrant is dark gray and contains the number '0'. The bottom quadrant is white and contains 'ND'. The left quadrant is black and contains '0'. The right quadrant is light gray and contains 'ND'.</p>	

Country- Specific Emergency
Phone Numbers

CHEMTREC In-Country Dial Numbers	Local # Provided in Country	Toll Free in Country*	Greeting Language
CHEMTREC South Africa*		0-800-983-611	English
CHEMTREC Argentina (Buenos Aires)	+(54)-1159839431		Latin American Spanish
CHEMTREC Brazil (Rio De Janeiro)	+(55)-2139581449		Portuguese
CHEMTREC Chile (Santiago)	+(56)-25814934		Latin American Spanish
CHEMTREC Colombia *		01800-710-2151	Latin American Spanish
CHEMTREC Mexico*		01-800-681-9531	Latin American Spanish
CHEMTREC Peru (Lima)	+(51)-17071295		Latin American Spanish
CHEMTREC China*	4001-204937		Mandarin
CHEMTREC Hong Kong (Hong Kong)*		800-968-793	Cantonese
CHEMTREC India *		000-800-100-7141	Hindi
CHEMTREC Indonesia *		001-803-017-9114	Indonesian
CHEMTREC Japan (Tokyo)	+(81)-345209637		Japanese
CHEMTREC Malaysia *		1-800-815-308	Malay
CHEMTREC Philippines *		1-800-1-116-1020	Tagalog
CHEMTREC Singapore*		800-101-2201	Mandarin
CHEMTREC Singapore	+(65)-31581349		Mandarin
CHEMTREC South Korea*		00-308-13-2549	Korean
CHEMTREC Taiwan*		00801-14-8954	Mandarin
CHEMTREC Thailand *		001-800-13-203-9987	Thai
CHEMTREC Vietnam (Ho Chi Minh City)	+(84)-838012436		Vietnamese
CHEMTREC Australia (Sydney)	+(61)-290372994		English
CHEMTREC Belgium (Brussels)	+(32)-28083237		French and Flemish
CHEMTREC Czech Republic (Prague)	+(420)-228880039		Czech
CHEMTREC France	+(33)-975181407		French
CHEMTREC Germany *		0800-181-7059	German
CHEMTREC Hungary (Budapest)	+(36)-18088425		Hungarian
CHEMTREC Italy *		800-789-767	Italian
CHEMTREC Italy (Milan)	+(39)-0245557031		Italian
CHEMTREC Netherlands	+(31)-858880596		Dutch
CHEMTREC Poland (Warsaw)	+(48)-223988029		Polish
CHEMTREC Spain*		900-868538	European Spanish
CHEMTREC Sweden (Stockholm)	+(46)-852503403		Swedish
CHEMTREC Switzerland (Zurich)	+(41)-435016715		German
CHEMTREC UK (London)	+(44)-870-8200418		English
CHEMTREC Bahrain (Bahrain)	+(973)-16199372		Arabic
CHEMTREC Israel (Tel Aviv)	+(972)-37630639		Hebrew
*Phone numbers for countries marked with an asterisk must be dialed within the country			

The information contained in this SDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information, and we assume no liability from its use.