

**Gliadel® Wafer****MATERIAL SAFETY DATA SHEET****1. PRODUCT AND COMPANY IDENTIFICATION**

Arbor Pharmaceuticals, Inc.  
980 Hammond Drive  
Suite 1250  
Atlanta, GA 30328

Technical Contact: Arbor Pharmaceuticals, Inc.  
Medical Information  
Tel: 1-866-516-4950  
Fax: 678-334-2433  
Email: [medinfo@arborpharma.com](mailto:medinfo@arborpharma.com)

Substance Name: Gliadel® Wafer, 3.5%  
Date Issued: February 12, 2013  
Manufacturer: Eisai® Inc.

Emergency Contact: CHEMTREC (800) 424-9300  
(24-hour contact for health and transportation emergencies)

**2. HAZARDS IDENTIFICATION**

Gliadel® Wafers are used for the treatment of high grade malignant gliomas in the brain. It is used in adjunct to surgery and radiation treatments. Carmustine, the active ingredient in Gliadel® Wafers is an animal carcinogen. Because Gliadel® Wafers are offered for sale in individual double sealed pouches, the availability of exposure via any route other than dermal is unlikely. Thus, exposure to the skin should be avoided as it can cause severe burning and hyperpigmentation to the skin.

**Potential Health Effects:**

<b>Route of Entry</b>	Skin contact/absorption
<b>Inhalation</b>	No information regarding inhalation
<b>Eye Contact</b>	No information regarding eye irritation
<b>Skin Contact</b>	No information regarding skin irritation
<b>Ingestion</b>	No information regarding ingestion

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

<b>Chemical Composition</b>	<b>% Composition</b>	<b>Exposure Limits</b>
Carmustine	3.85	2 µg/m <sup>3</sup>
Biodegradable polyanhydride copolymer	96.15	Not established
	100	
<b>CAS #</b>	154-93-8 (Carmustine)	
<b>NIOSH/RTECS NO.</b>	Not Established for the Formulation	

**Gliadel® Wafer****MATERIAL SAFETY DATA SHEET****4. FIRST AID MEASURES**

Short-term toxic effects of this compound in humans are unknown. Therefore, the following general precautions should be observed.

Ingestion	Consult a physician immediately. Never give anything by mouth to someone who is unconscious or convulsing.
Inhalation	Move victim to fresh air and keep them warm and quiet. If not breathing, administer artificial respiration. Get immediate medical attention.
Eye contact	Flush eyes with clean running water for at least 15 minutes. Contact a physician.
Skin contact	Exposure to the skin can cause severe burning and hyperpigmentation to the skin. Contact a physician.

**5. FIRE FIGHTING MEASURES**

<b>Flash Point (Closed Cup)</b>	N/A
<b>Flammable Limits</b>	Upper – N/A % Lower-N/A %
<b>Autoignition Temperature</b>	Unknown
<b>Extinguishing Media</b>	Non-flammable material. Use dry chemical, carbon dioxide, foam or water spray as appropriate for the surrounding fire and materials.
<b>Special Fire Fighting Procedures</b>	Non-flammable. Wear protective clothing and self-contained breathing apparatus as appropriate for surrounding fire. Firefighters Should Wear Proper Protective Equipment And Self-Contained Breathing Apparatus With Full Facepiece Operated in Positive Pressure Mode.

**6. ACCIDENTAL RELEASE MEASURES**

Prevent migration into the environment. In the dry state the carmustine is bound in the copolymer material and is not readily released. Sweep or pick up material and place in appropriate waste (always wear gloves or use forceps). Dispose according to all applicable laws and regulations. Wash area of spill with soap and water.

**7. HANDLING AND STORAGE**

Storage	Per the prescribing information, this compound should be stored at or below -20° C. For the Canada and Japan regions, stored at or below -15°C.
---------	---

1. The wafers are in sterile form and individually packaged for surgical application.
2. Handling should be performed only by personnel wearing double gloves. Only use surgical instruments that are dedicated for use with Gliadel® Wafers. Handle according to the surgical procedures accompanying the package.

**Gliadel® Wafer****MATERIAL SAFETY DATA SHEET****8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

<b>Ventilation</b>	Not required during normal handling
<b>Respiratory Protection</b>	None required during normal handling or when engineering controls are sufficient.
<b>Eye/Skin Protection</b>	Wear chemically resistant gloves, and lab coats or other body covering to minimize potential for skin contact. Safety glasses are always required.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

<b>Boiling Point</b>	Not Available
<b>Vapor Pressure (Mm Hg)</b>	Unknown
<b>Melting Point</b>	Not Available
<b>Vapor Density (Air=1)</b>	Unknown
<b>Specific Gravity</b>	Unknown
<b>Evaporation Rate</b>	Unknown
<b>Hygroscopicity</b>	Unknown
<b>Ph (Aqueous)</b>	solid
<b>Solubility</b>	Carmustine is soluble in DCM, Ethanol, Methanol, and Ether
<b>% Volatiles By Volume</b>	N/A
<b>Appearance &amp; Odor</b>	White to almost white wafer

**10. STABILITY AND REACTIVITY DATA**

<b>Stability</b>	Material is stable under normal conditions of temperature and pressure.
<b>Hazardous Polymerization</b>	Unknown
<b>Conditions to Avoid</b>	None identified
<b>Decomposition Products</b>	Unknown
<b>Incompatible materials</b>	Unknown

**Gliadel® Wafer****MATERIAL SAFETY DATA SHEET****11. TOXICOLOGICAL INFORMATION**

<b>Mechanism of Action:</b>	Carmustine: Bone marrow, lungs, liver, gastrointestinal tract, kidney and male reproductive organs.
<b>Toxicity of Carmustine:</b>	LD <sub>50</sub> <u>Oral:</u> 20 mg/kg (rat); 19 mg/kg (mouse) <u>Intraperitoneal:</u> 17.42 mg/kg (rat); 21.26 mg/kg (mouse); <u>Intravenous:</u> 13.8 mg/kg; 45 mg/kg (mouse); <u>Intramuscular:</u> 79.6 mg/kg (rat); 86.3 mg/kg (mouse); <u>Subcutaneous:</u> 83.2 mg/kg (rat); 24 mg/kg (mouse)
<b>Carcinogenicity of Carmustine:</b>	NTP: Listed IARC: 2A Z List: No OSHA Reg: N/D Carmustine is considered a carcinogen in animals.
<b>Teratogenicity of Carmustine:</b>	Carmustine has shown to be a teratogen at 0.5, 1, 2, 4, or 8 mg/kg/day in rats in intraperitoneal doses. Also shown to be teratogenic in rabbits at 4 mg/kg/day. Carmustine may cause fetal harm when exposed to a pregnant woman.
<b>Effects of Overexposure</b>	Exposure to skin will result in severe burns and hyperpigmentation.
<b>Target Organs</b>	Not established
<b>Medical Conditions Generally Aggravated By Exposure</b>	Pregnancy
<b>Routes of Entry</b>	Skin contact

**12. ECOLOGICAL INFORMATION**

No information at this time.

**13. DISPOSAL CONSIDERATIONS**

Disposal Procedure: Dispose in accordance with all applicable federal, state, and local environmental regulations.

**14. TRANSPORTATION DATA AND ADDITIONAL INFORMATION**

DOT/IATA: Non Regulated  
 ICAO: Non Regulated  
 IMO: Non Regulated  
 Shipping Conditions: This product must be shipped at or below -20° C (-4° F) and is shipped marked as: dry ice UN1845 in a PGIII thermo insulated fiberboard package.

**15. REGULATORY INFORMATION**

Non-regulated

**Gliadel<sup>®</sup> Wafer**

**MATERIAL SAFETY DATA SHEET**

**16. OTHER INFORMATION**

---

In case of overexposure, please contact CHEMTREC 800-424-9300, Internationally 703-527-3887

---

The information contained herein is provided in good faith and is believed to be correct as of the date hereof. However, Arbor makes no representation as to the comprehensiveness or accuracy of the information. It is expected that individuals receiving the information will exercise their independent judgment in determining its appropriateness for a particular purpose. Accordingly, Arbor will not be responsible for damages of any kind resulting from the use of or reliance upon such information.

NO REPRESENTATIONS, OR WARRANTIES, EITHER EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER NATURE ARE MADE HEREUNDER WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR TO THE PRODUCT TO WHICH THE INFORMATION REFERS.

EISAI<sup>®</sup> is a registered trademark of Eisai R&D Management Co., Ltd. licensed to Arbor Pharmaceuticals, Inc.

GLIADEL<sup>®</sup> is a registered trademark of Eisai Inc. licensed to Arbor Pharmaceuticals, Inc.