

# SAFETY DATA SHEET

## 1 PRODUCT AND COMPANY IDENTIFICATION

**Product name:** TEMOZOLOMIDE STERILE POWDER FOR INJECTION      **SDS No:** P00000021002

**Synonyms, Trade Names:**  
TEMODAR, TEMODAL, TEMODAR Powder for Injection

**Manufacturer:**  
Merck  
One Merck Drive P.O. Box 100  
Whitehouse Station, NJ, USA 08889-0100

**Telephone:** 908-423-1000 (General Information Only)  
**Fax:** 908-735-1496

**Contact Person:** EHS Data Steward  
**e-mail:** MSDS@merck.com

**Emergency telephone:** 1-908-423-6000  
(24/7/365) English Only

**Intended Use:** Finished pharmaceutical product.

## 2 HAZARDS IDENTIFICATION

### Emergency Overview:

**Appearance:**

**Color:** White  
**Form :** Powder  
**Odor:** Unknown

**Signal words** CAUTION!

**Potential Health Effects:**

**General** Finished pharmaceutical product. Toxic if swallowed. May cause genetic defects. May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Do not breathe dust. Do not handle until all safety precautions have been read and understood. Use only outdoors or in a well-ventilated area. Do not eat, drink or smoke when using the product. Wash thoroughly after handling.

**Potential Physical / Chemical Effects:**

Under normal conditions of use, this material is not expected to present a significant fire or explosion hazard. This material may present a dust deflagration hazard if sufficient quantities are or may become suspended in air. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

**Inhalation:** None expected with normal handling of finished product.

**skin:** None expected with normal handling of finished product.

**eye:** None expected with normal handling of finished product.

<b>Ingestion:</b>	None expected with normal handling of finished product.
<b>Target Organs:</b>	bone marrow, lymph nodes, testes, gastrointestinal tract, mammary gland
<b>OSHA Regulatory Status</b>	This product is hazardous according to OSHA 29CFR 1910.1200.
<b>Environment:</b>	The product is not expected to be hazardous to the environment.
<b>OTHER INFORMATION</b>	Causes effects to the blood. Causes effects to the immune system. May cause bone marrow effects. May cause gastrointestinal effects. May cause effects to the male reproductive system. May cause effects to the fetus.

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

**General information:** The formulations for these products are proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the composition table. Active ingredients in any concentration are listed.

**Hazardous Component(s):**

Chemical name	CAS-No.	Concentration
Temozolomide	85622-93-1	7.8%
HYDROCHLORIC ACID	7647-01-0	4.6%

\* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

### 4 FIRST AID MEASURES

<b>Inhalation:</b>	Move into fresh air and keep at rest. For breathing difficulties, oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.
<b>Skin contact:</b>	Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.
<b>Eye contact:</b>	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
<b>Ingestion:</b>	Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.
<b>Notes to the physician:</b>	
<b>Hazards:</b>	See Sections 2 and 11.
<b>Treatment:</b>	Treat supportively and symptomatically.

### 5 FIRE-FIGHTING MEASURES

<b>Extinguishing media:</b>	Water spray, fog, CO2, dry chemical, or alcohol resistant foam.
<b>Unsuitable extinguishing media:</b>	None known.
<b>Unusual Fire &amp; Explosion Hazards:</b>	Emits toxic fumes under fire conditions.

**Special Fire Fighting Procedures:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Protective Measures:** Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

## 6 ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures.

**Environmental precautions:** Do not release into the environment.

**Spill Cleanup Methods:** Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

## 7 HANDLING AND STORAGE

**Handling:** Do not handle until all safety precautions have been read and understood. Do not breathe dust. Do not get in eyes, on skin, on clothing. Wash thoroughly after handling.

**Storage:** Keep container tightly closed in a cool, well-ventilated place.

## 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure limits:

Chemical name	Type	Exposure Limit values	Source
HYDROCHLORIC ACID	Ceiling	2 ppm	US. ACGIH Threshold Limit Values (2009)
HYDROCHLORIC ACID	Ceiling	5 ppm                      7 mg/m <sup>3</sup>	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Temozolomide	TWA	0.6 ug/m <sup>3</sup> (OEB 5)	Merck
	Wipe Limit	6 ug/100cm <sup>2</sup>	Merck

OEB (Occupational Exposure Band) is an internal Merck control band.

**Protective Measures:** Observe occupational exposure limits and minimize the risk of inhalation of dust. No open handling permitted. Closed systems are required to control at source (e.g., glove boxes/isolators). Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

**Respiratory Protection:** Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. When handling a compound in solution, a cartridge/canister appropriate for the solution may also be needed. Use redundant respiratory protection as a prudent practice for adjunct protection in addition to effective engineering controls. Powered air filter

respirator. Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabilities, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.

**Hand protection:** Chemical resistant gloves. Consider double gloving.

**Eye protection:** Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and Body Protection:** Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hygiene measures:** Wash skin thoroughly with soap and water.

## 9 PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

**Appearance:**

<b>Physical State:</b>	Solid
<b>Form:</b>	Powder
<b>Color:</b>	White
<b>Odor:</b>	Unknown

## 10 STABILITY AND REACTIVITY

<b>Stability:</b>	Stable
<b>Possibility of hazardous reactions:</b>	Stable
<b>Conditions to avoid:</b>	Excessive heat. Moisture.
<b>Incompatible materials:</b>	No data available.
<b>Hazardous decomposition products:</b>	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

## 11 TOXICOLOGICAL INFORMATION

**General information:** The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

**Specified substance(s):**

<b>Acute Toxicity (Oral); Name</b>	<b>Test results</b>
Temozolomide	LD50 (Dog): 20 mg/kg Moderately toxic. LD50 (Rat): 328 mg/kg LD50 (Mouse, Male): 297 mg/kg LD50 (Mouse, Female): 357 mg/kg
HYDROCHLORIC ACID	LD50 (Rabbit): 900 mg/kg
<b>Acute Toxicity (Dermal); Name</b>	<b>Test results</b>
Temozolomide	(Rabbit): Mild skin irritation
HYDROCHLORIC ACID	LD50 (Mouse): 1,449 mg/kg
<b>Acute Toxicity (Inhalation); Name</b>	<b>Test results</b>
Temozolomide	No data available.
HYDROCHLORIC ACID	LC50 (Mouse, 1 h): 1,108 mg/l LC50 (, , 1 h): 3,124 mg/l
<b>Repeated dose toxicity; Name</b>	<b>Test results</b>
Temozolomide	NOEL (Dog, Oral, 28 d): 2.5 mg/kg (Target Organ(s): bone marrow, lymph nodes, testes, gastrointestinal tract) NOEL (Rat, Oral, 28 d): 8.5 mg/kg (Target Organ(s): bone marrow, lymph nodes, testes, gastrointestinal tract) NOEL (Rat(Male), Oral, 28 d): 4 mg/kg (Target Organ(s): mammary gland)
<b>Inhalation:</b>	None expected with normal handling of finished product.
<b>Ingestion:</b>	None expected with normal handling of finished product.
<b>Skin corrosion/irritation:</b>	None expected with normal handling of finished product.
<b>Serious eye damage/eye irritation:</b>	None expected with normal handling of finished product.
<b>Respiratory sensitizer/Skin sensitizer:</b>	Active pharmaceutical ingredient: Not a dermal sensitizer in Guinea Pig.
<b>Carcinogenicity:</b>	Active pharmaceutical ingredient: May cause cancer.
<b>Mutagenesis:</b>	Active pharmaceutical ingredient: Positive in in vitro and in vivo genotoxicity assays.
<b>Reproductive toxicity:</b>	Active pharmaceutical ingredient: Decreased fertility was observed in male rats. Caused teratogenic effects in animals. Decreased fertility was observed in male rabbits.
<b>Other Effects:</b>	No additional information

**12 ECOLOGICAL INFORMATION**

**General information:** The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

**Ecotoxicity:**

**Product:**

**Chronic Toxicity(Fish):** No data available.

**Chronic Toxicity(Aquatic invertebrates):** No data available.

**Specified substance(s):**

**Acute toxicity(Fish):**

Name	Test results
Temozolomide	LC50 (Rainbow Trout ( <i>Oncorhynchus mykiss</i> ), 96 h): > 100 mg/l
HYDROCHLORIC ACID	LC50 (Western mosquitofish ( <i>Gambusia affinis</i> ), 96 h): 282 mg/l Mortality

**Acute toxicity(Aquatic invertebrates):**

Name	Test results
Temozolomide	EC 50 (Water flea ( <i>Daphnia magna</i> ), 48 h): > 100 mg/l
HYDROCHLORIC ACID	LC50 (Common shrimp ( <i>Crangon crangon</i> ), 48 h): 260 mg/l Mortality LC50 (Green or European shore crab ( <i>Carcinus maenas</i> ), 48 h): 240 mg/l Mortality

**Acute toxicity(Aquatic plants):**

Name	Test results
Temozolomide	EC 50 (Green algae ( <i>Pseudokirchneriella subcapitata</i> ), 72 h): 75 mg/l (biomass) EC 50 (Green algae ( <i>Pseudokirchneriella subcapitata</i> ), 72 h): > 90 mg/l (growth) NOEC (Green algae ( <i>Pseudokirchneriella subcapitata</i> ), 72 h): 40 mg/l

**Persistence and degradability:** Active pharmaceutical ingredient: Expected to biodegrade.

**Bioaccumulative potential:** Active pharmaceutical ingredient: Not likely to bioaccumulate based on log Kow

**Mobility:** Active pharmaceutical ingredient: Expected to be mobile in soil.

**13 DISPOSAL CONSIDERATIONS**

**Disposal Methods:** Disposal must be in accordance with applicable national, state/provincial, and/or local regulations.

**Measures for Avoidance and Recovery:** Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

**14 TRANSPORT INFORMATION**

**DOT**

Not regulated.

**IMDG - International Maritime Dangerous Goods Code**

Not regulated.

**IATA - International Air Transport Association**  
 Not regulated.

<b>15 REGULATORY INFORMATION</b>
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**US Regulations**

- **CERCLA Hazardous Substance List (40 CFR 302.4):**  
     HYDROCHLORIC ACID                      Reportable quantity: 5000 lbs.
  
- **Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):**  
     HYDROCHLORIC ACID                      Reportable quantity: 5000 lbs.
  
- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):**  
     HYDROCHLORIC ACID                      Threshold quantity: 5000 lbs  
     HYDROCHLORIC ACID                      Threshold quantity: 15000 lbs

**SARA Title III**

- **Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):**

Chemical name	RQ	Threshold Planning Quantity
HYDROCHLORIC ACID	5000 lbs.	500 CUST- ARI011000000013.

- **Section 313 Toxic Release Inventory (40 CFR 372):**

Chemical name	CAS-No.	Reporting threshold for other users	Reporting threshold for manufacturing and processing
HYDROCHLORIC ACID	7647-01-0	10000 CUST- ARI011000000013	25000 CUST- ARI011000000013.

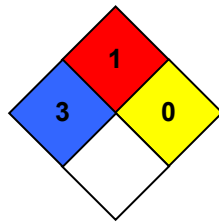
**State Regulations**

- **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**  
     No ingredient regulated by CA Prop 65 present.
  
- **Massachusetts Right-To-Know List:**  
     HYDROCHLORIC ACID                      Listed
  
- **New Jersey Right-To-Know List:**  
     HYDROCHLORIC ACID                      Listed
  
- **Pennsylvania Right-To-Know List:**  
     HYDROCHLORIC ACID                      Listed

<b>16 OTHER INFORMATION</b>
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**OTHER INFORMATION**

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

**NFPA Hazard ID**

Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe

**Revision Information:**

Not relevant.

**Issue Date:**

21.01.2014

**Disclaimer:**

This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.