

## Temozolomide Injection Formulation

Version 13.0      Revision Date: 05/09/2026      SDS Number: 27554-00028      Date of last issue: 12/06/2025  
Date of first issue: 11/03/2014

---

### SECTION 1. IDENTIFICATION

Product name : Temozolomide Injection Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable



---

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Eye irritation : Category 2A  
Germ cell mutagenicity : Category 2  
Carcinogenicity : Category 2  
Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 1 (Bone marrow, thymus gland, Lymph nodes, spleen)  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms :  

Signal Word : Danger

Hazard Statements : H319 Causes serious eye irritation.  
H341 Suspected of causing genetic defects.  
H351 Suspected of causing cancer.  
H360FD May damage fertility. May damage the unborn child.  
H372 Causes damage to organs (Bone marrow, thymus gland, Lymph nodes, spleen) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version 13.0      Revision Date: 05/09/2026      SDS Number: 27554-00028      Date of last issue: 12/06/2025  
Date of first issue: 11/03/2014

P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

### Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P337 + P313 If eye irritation persists: Get medical attention.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Citric acid	2-hydroxypropane-1,2,3-tricarboxylic acid	77-92-9*	>= 7 - <= 13	TSC
Temozolomide	No data available	85622-93-1*	>= 5 - <= 10	TSC

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version 13.0      Revision Date: 05/09/2026      SDS Number: 27554-00028      Date of last issue: 12/06/2025  
Date of first issue: 11/03/2014

---

- In case of eye contact : Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.  
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Causes serious eye irritation.  
Suspected of causing genetic defects.  
Suspected of causing cancer.  
May damage fertility. May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure if swallowed.  
Contact with dust can cause mechanical irritation or drying of the skin.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- ||Notes to physician : Treat symptomatically and supportively.
- 

### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Metal oxides  
Chlorine compounds
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
13.0	05/09/2026	27554-00028	Date of first issue: 11/03/2014

---

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
- 

### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.
-

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version 13.0      Revision Date: 05/09/2026      SDS Number: 27554-00028      Date of last issue: 12/06/2025  
Date of first issue: 11/03/2014

Materials to avoid : Keep tightly closed.  
Store in accordance with the particular national regulations.  
: Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Temozolomide	85622-93-1	TWA	0.1 ug/m3 (OEB 5)	Internal
		Wipe limit	1 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.  
Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
No open handling permitted.  
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.

#### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Filter type : Particulates type  
Hand protection

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version 13.0      Revision Date: 05/09/2026      SDS Number: 27554-00028      Date of last issue: 12/06/2025  
Date of first issue: 11/03/2014

---

Material	:	Chemical-resistant gloves
Remarks	:	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	:	Work uniform or laboratory coat. 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	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

---

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
13.0	05/09/2026	27554-00028	Date of first issue: 11/03/2014

---

Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics Particle size	:	No data available

---

### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version 13.0      Revision Date: 05/09/2026      SDS Number: 27554-00028      Date of last issue: 12/06/2025  
Date of first issue: 11/03/2014

---

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

#### Components:

##### Citric acid:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg  
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

##### Temozolomide:

Acute oral toxicity : LD50 (Dog): 19 mg/kg  
LD50 (Rat): 315 mg/kg  
LD50 (Mouse): 205 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Citric acid:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

#### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Components:

##### Citric acid:

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version 13.0      Revision Date: 05/09/2026      SDS Number: 27554-00028      Date of last issue: 12/06/2025  
Date of first issue: 11/03/2014

---

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

##### Temozolomide:

Test Type	:	Maximization Test
Routes of exposure	:	Dermal
Species	:	Guinea pig
Result	:	negative

### Germ cell mutagenicity

Suspected of causing genetic defects.

#### Components:

##### Citric acid:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: in vitro micronucleus test Result: positive
		Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative

##### Temozolomide:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: positive
		Test Type: Chromosome aberration test in vitro Test system: Human lymphocytes Result: positive
Germ cell mutagenicity - Assessment	:	Positive results from in vitro mammalian mutagenicity assays, chemical structure activity relationship to known germ cell mutagens

### Carcinogenicity

Suspected of causing cancer.



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version 13.0      Revision Date: 05/09/2026      SDS Number: 27554-00028      Date of last issue: 12/06/2025  
Date of first issue: 11/03/2014

---

### Components:

#### **Temozolomide:**

Routes of exposure : Ingestion  
Target Organs : Bone marrow, thymus gland, Lymph nodes, spleen  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

#### Components:

#### **Citric acid:**

Species : Rat  
NOAEL : 4,000 mg/kg  
LOAEL : 8,000 mg/kg  
Application Route : Ingestion  
Exposure time : 10 Days

#### **Temozolomide:**

Species : Rat, female  
NOAEL : 4 mg/kg  
LOAEL : 21 mg/kg  
Application Route : Oral  
Exposure time : 6 Months  
Target Organs : thymus gland, Bone marrow, Reproductive organs, Lymph nodes

Species : Rat, male  
NOAEL : 8.5 mg/kg  
LOAEL : 34 mg/kg  
Application Route : Oral  
Exposure time : 6 Months  
Target Organs : thymus gland, Bone marrow, male reproductive organs, Gastrointestinal tract, Lymph nodes

Species : Dog  
NOAEL : 2.5 mg/kg  
LOAEL : 6.3 mg/kg  
Application Route : Oral  
Exposure time : 6 Months  
Target Organs : Bone marrow, spleen, male reproductive organs, Gastrointestinal tract, thymus gland

### **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

#### Components:

#### **Temozolomide:**

Ingestion : Symptoms: Blood disorders, Nausea, Vomiting, Diarrhea,



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version 13.0      Revision Date: 05/09/2026      SDS Number: 27554-00028      Date of last issue: 12/06/2025  
Date of first issue: 11/03/2014

---

Exposure time: 35 d  
Stability in water : Degradation half life (DT50): < 1 d

### Bioaccumulative potential

#### Components:

##### **Citric acid:**

Partition coefficient: n-octanol/water : log Pow: -1.72

##### **Temozolomide:**

Partition coefficient: n-octanol/water : log Pow: 1.35

##### **Mobility in soil**

No data available

##### **Other adverse effects**

No data available

##### **Endocrine disrupting properties**

No data available

---

## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

---

## SECTION 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

#### **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

#### **Domestic regulation**

#### **TDG**

Not regulated as a dangerous good

---

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
13.0	05/09/2026	27554-00028	Date of first issue: 11/03/2014

### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

### The ingredients of this product are reported in the following inventories:

AICS : not determined

CA. DSL : not determined

CN IECSC : not determined

### Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
13.0	05/09/2026	27554-00028	Date of first issue: 11/03/2014

---

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 05/09/2026  
Date format : mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8