

## Temozolomide Formulation

Version 8.2      Revision Date: 12/06/2025      SDS Number: 25432-00029      Date of last issue: 04/14/2025  
Date of first issue: 10/24/2014

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### SECTION 1. IDENTIFICATION

Product name : Temozolomide 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

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### SECTION 2. HAZARDS IDENTIFICATION

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

Acute toxicity (Oral) : Category 4  
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 : H302 Harmful if swallowed.  
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.

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Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
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:**  
P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.  
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.	Concentration (% w/w)
Temozolomide	No data available	85622-93-1	$\geq 30 - < 60$ *
Stearic acid	Octadecanoic acid	57-11-4	$\geq 1 - < 5$ *
(+)-Tartaric acid	(2R,3R)-2,3-Dihydroxybutanedioic acid	87-69-4	$\geq 1 - < 5$ *

\* 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.

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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. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	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. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	Harmful if swallowed. 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. No information available.
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.

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### 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
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

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so.  
Evacuate area.

Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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### 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.

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### 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.

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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.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

Materials to avoid : 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/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	1 µg/100 cm <sup>2</sup>	Internal
Stearic acid	57-11-4	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Inhalable)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (inhalable dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWAEV (respirable aerosol fraction)	3 mg/m <sup>3</sup>	CA QC OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

**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

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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
- 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.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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Appearance	:	powder
Color	:	off-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	:	No data available
Evaporation rate	:	No data available
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
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1 g/cm <sup>3</sup>
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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Molecular weight : No data available

Particle characteristics  
Particle size : No data available

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### 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.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 559.98 mg/kg  
Method: Calculation method

#### Components:

##### Temozolomide:

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

##### Stearic acid:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 2 mg/l  
Exposure time: 1 h  
Test atmosphere: vapor

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Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

### **(+)-Tartaric acid:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423

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

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **Stearic acid:**

Species : Rabbit  
Method : Patch Test 24 Hrs.  
Result : No skin irritation

#### **(+)-Tartaric acid:**

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

### **Serious eye damage/eye irritation**

Causes serious eye irritation.

### **Components:**

#### **Stearic acid:**

Species : Rabbit  
Result : No eye irritation

#### **(+)-Tartaric acid:**

Species : Bovine cornea  
Method : OECD Test Guideline 437  
Result : Irreversible effects on the eye

### **Respiratory or skin sensitization**

#### **Skin sensitization**

Not classified based on available information.

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### Respiratory sensitization

Not classified based on available information.

#### Components:

##### **Temozolomide:**

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

##### **Stearic acid:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

##### **(+)-Tartaric acid:**

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative

### Germ cell mutagenicity

Suspected of causing genetic defects.

#### Components:

##### **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

##### **Stearic acid:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

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Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

### **(+)-Tartaric acid:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Result: negative  
Remarks: Based on data from similar materials

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: positive

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

### **Carcinogenicity**

Suspected of causing cancer.

#### **Components:**

##### **Temozolomide:**

Species : Rat  
Application Route : Oral  
Exposure time : 6 Months  
: 4 mg/kg body weight  
Result : positive  
Target Organs : Mammary gland

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

### **Reproductive toxicity**

May damage fertility. May damage the unborn child.

#### **Components:**

##### **Temozolomide:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat, male  
Application Route: Oral  
Fertility: LOAEL: 8.5 mg/kg body weight  
Result: positive

Effects on fetal development : Test Type: Embryo-fetal development

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Species: Rat  
Application Route: Oral  
Embryo-fetal toxicity.: LOAEL: 13 mg/kg body weight  
Result: positive, Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

### Stearic acid:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

### (+)-Tartaric acid:

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Bone marrow, thymus gland, Lymph nodes, spleen) through prolonged or repeated exposure if swallowed.

### 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.

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### Repeated dose toxicity

#### Components:

##### **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

##### **Stearic acid:**

Species : Rat  
NOAEL : 1,000 mg/kg  
Application Route : Ingestion  
Exposure time : 42 Days  
Method : OECD Test Guideline 422  
Remarks : Based on data from similar materials

##### **(+)-Tartaric acid:**

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 2 y

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### **Temozolomide:**

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

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anorexia, Fatigue, hair loss

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### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Temozolomide:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 90 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 40 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- Toxicity to microorganisms : EC50: > 100 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

##### **Stearic acid:**

- Toxicity to fish : LL50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l  
Exposure time: 48 h  
Method: DIN 38412
- Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 10 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.
- Toxicity to algae/aquatic plants : NOELR (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.
- EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h

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Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOELR (Daphnia magna (Water flea)): > 0.5 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.

Toxicity to microorganisms : EC10 (Pseudomonas putida): 883 mg/l  
Exposure time: 18 h

### **(+)-Tartaric acid:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 93.313 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 51.404 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 3.125 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

### **Persistence and degradability**

#### **Components:**

##### **Temozolomide:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 83 %  
Exposure time: 35 d

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

##### **Stearic acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 71 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

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### **(+)-Tartaric acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 85 %  
Exposure time: 28 d  
Method: OECD Test Guideline 306

### **Bioaccumulative potential**

#### **Components:**

##### **Temozolomide:**

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

##### **Stearic acid:**

Partition coefficient: n-octanol/water : log Pow: 8.23

##### **(+)-Tartaric acid:**

Partition coefficient: n-octanol/water : log Pow: -1.91

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

No data available

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

No data available

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## 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.

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## 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.

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# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Temozolomide Formulation

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### Domestic regulation

#### TDG

Not regulated as a dangerous good

#### 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

IECSC : not determined

### Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)  
CA BC OEL : Canada. British Columbia OEL  
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants  
ACGIH / TWA : 8-hour, time-weighted average  
CA AB OEL / TWA : 8-hour Occupational exposure limit  
CA BC OEL / TWA : 8-hour time weighted average  
CA QC OEL / TWA EV : Time-weighted average exposure value

AICC - 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

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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; TECI - 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

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 : 12/06/2025  
Date format : mm/dd/yyyy

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.

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