

## Temozolomide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.0	19.12.2024	25451-00025	Date of first issue: 24.10.2014

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Temozolomide Formulation

**Manufacturer or supplier's details**

Company name of supplier	: MSD
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@msd.com

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


Recommended use	: Pharmaceutical
Restrictions on use	: Not applicable

## SECTION 2. HAZARDS IDENTIFICATION

**GHS Classification**

Acute toxicity (Oral)	: Category 4
Serious eye damage/eye irritation	: Category 2A
Germ cell mutagenicity	: Category 2
Carcinogenicity	: Category 2
Reproductive toxicity	: Category 1B
Specific target organ toxicity - repeated exposure (Oral)	: Category 1 (Bone marrow, thymus gland, Lymph nodes, spleen)

**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.
Precautionary Statements	: <b>Prevention:</b>

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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/ face protection.

**Response:**

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician 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 advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ 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	CAS-No.	Concentration (% w/w)
Temozolomide	85622-93-1	$\geq 50$ - $< 70$
Stearic acid	57-11-4	$\geq 1$ - $< 5$
(+)-Tartaric acid	87-69-4	$\geq 1$ - $< 3$

**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.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.

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|---|--|
| In case of eye contact                                      | : Thoroughly clean shoes before reuse.<br>In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.   |
| If swallowed  | : If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person.  |
| Most important symptoms and effects, both acute and delayed | : Contact with dust can cause mechanical irritation or drying of the skin.<br>Harmful if swallowed.<br>Causes serious eye irritation.<br>Suspected of causing genetic defects.<br>Suspected of causing cancer.<br>May damage fertility. May damage the unborn child.<br>Causes damage to organs through prolonged or repeated exposure if swallowed. |
| 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                  | : Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )<br>Metal oxides   |
| Specific extinguishing methods                 | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

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- 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.
- 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.

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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.

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/m3 (OEB 5)	Internal
		Wipe limit	1 µg/100 cm2	Internal
Stearic acid	57-11-4	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		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 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.

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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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

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,

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	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.
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  
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:



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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.**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

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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  
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

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**Carcinogenicity****II** 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
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**Reproductive toxicity****II** 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
	:	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.
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**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

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**(+)-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.

**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

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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, 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

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**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  
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

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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

**(+)-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

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

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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****NOM-002-SCT**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, : Not applicable  
essential chemical products and machinery for  
producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**

Revision Date : 19.12.2024  
Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting  
the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits  
ACGIH / TWA : 8-hour, time-weighted average



**Temozolomide Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.0	19.12.2024	25451-00025	Date of first issue: 24.10.2014

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NOM-010-STPS-2014 / VLE- : Time weighted average limit value  
PPT

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 Standardisation; 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 Organisation 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; 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, Authorisation 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

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/>

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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