

Temozolomide Formulation

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|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024 |
| 8.0 | 19.12.2024 | 25426-00027 | Date of first issue: 24.10.2014 |

SECTION 1: IDENTIFICATION

Product name : Temozolomide Formulation

Manufacturer or supplier's details

Company : MSD

Address : Building A - Level 1/26 Talavera Rd
Macquarie Park NSW, Australia 2113

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

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.

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Precautionary statements :

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.

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/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ 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 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 which do not result in classification

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 | >= 30 -< 60 |
| Stearic acid | 57-11-4 | < 10 |
| (+)-Tartaric acid | 87-69-4 | >= 1 -< 3 |

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

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| | vice 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. 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 | : Contact with dust can cause mechanical irritation or drying of the skin. 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. |
| 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. FIREFIGHTING MEASURES

| | |
|---------------------------------------|---|
| Suitable extinguishing media | : Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 _x) Metal oxides |
| Specific extinguishing method | : Use extinguishing measures that are appropriate to local cir- |

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ods cumstances 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 : In the event of fire, wear self-contained breathing apparatus.
for firefighters Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Use personal protective equipment.
tive equipment and emer- Follow safe handling advice (see section 7) and personal pro-
gency procedures tective 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 : Sweep up or vacuum up spillage and collect in suitable con-
containment and cleaning up tainer 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 as-

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- 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.
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 labelled 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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 | TWA | 10 mg/m3 | AU OEL |
| | | TWA (Inhalable particulate matter) | 10 mg/m3 | ACGIH |
| | | TWA (Respirable particulate matter) | 3 mg/m3 | 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, includ-

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ing 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. |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|-----------------|---|-------------------|
| Appearance | : | powder |
| Colour | : | off-white |
| Odour | : | No data available |
| Odour Threshold | : | No data available |

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| | | |
|--|---|---|
| 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 |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | 1 g/cm ³ |
| Solubility(ies) Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Auto-ignition 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

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| 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. |

SECTION 11. TOXICOLOGICAL INFORMATION

| | | |
|-----------------|---|--|
| Exposure routes | : | Inhalation Skin contact Ingestion Eye contact |
|-----------------|---|--|

Acute toxicity

|| Harmful if swallowed.

Product:

| | | |
|---------------------|---|--|
| Acute oral toxicity | : | Acute toxicity estimate: 562.5 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:

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|---------------------------|---|--|
| 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: vapour 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 |

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(+)-Tartaric acid:

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|-----------------------|---|---|
| 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 sensitisation**Skin sensitisation**

|| Not classified based on available information.

Respiratory sensitisation

|| Not classified based on available information.

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Components:**Temozolomide:**

| | | |
|-----------------|---|-------------------|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Dermal |
| Species | : | Guinea pig |
| Result | : | negative |

Stearic acid:

| | | |
|-----------------|---|--------------------------------------|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

(+)-Tartaric acid:

| | | |
|-----------------|---|-------------------------------|
| Test Type | : | Local lymph node assay (LLNA) |
| Exposure routes | : | Skin contact |
| Species | : | Mouse |
| Method | : | OECD Test Guideline 429 |
| Result | : | negative |

Chronic toxicity**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:

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|-----------------------|---|--|
| 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

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Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal 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 foetal 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 foetal development : Test Type: Embryo-foetal 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:**

Exposure routes : 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:**

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|-------------------|---|
| 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:

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|-------------------|--|
| 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 yr |

Aspiration toxicity

|| Not classified based on available information.

Experience with human exposure**Components:****Temozolomide:**

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Ingestion : Symptoms: Blood disorders, Nausea, Vomiting, Diarrhoea, anorexia, Fatigue, hair loss

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Temozolomide:**

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| 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:

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|---|---|
| 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 |

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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
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

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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.

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**

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable

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Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

National Regulations**ADG**

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

Special precautions for user

Not applicable

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

Therapeutic Goods (Poisons Standard) Instrument : No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)
Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of

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the model WHS Act and Regulations.

The components of this product are reported in the following inventories:

| | | |
|-------|---|----------------|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

SECTION 16: ANY OTHER RELEVANT INFORMATION**Further information**

| | | |
|---|---|---|
| Revision Date | : | 19.12.2024 |
| Sources of key data used to compile the 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.

| | | |
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| Date format | : | dd.mm.yyyy |
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Full text of other abbreviations

| | | |
|--------|---|--|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| AU OEL | : | Australia. Workplace Exposure Standards for Airborne Contaminants. |

| | | |
|--------------|---|---|
| ACGIH / TWA | : | 8-hour, time-weighted average |
| AU OEL / TWA | : | Exposure standard - time weighted average |

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 Develop-

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ment; 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; 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

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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