

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

**SECTION 1. IDENTIFICATION**

Product identifier : Temozolomide Injection Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Avenida Tanner de Melo, Quadra 10 Lote 4A, Galpão A  
Parque Industrial Vice Presidente José Alencar Aparecida de  
Goiás – GO, Brazil

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 in accordance with ABNT NBR 14725 Standard**

Acute toxicity (Oral) : Category 5

Eye irritation : Category 2A

Germ cell mutagenicity : Category 2

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Bone marrow, thymus gland, Lymph nodes, spleen)

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.  
H319 Causes serious eye irritation.  
H341 Suspected of causing genetic defects.

## Temozolomide Injection Formulation

Version 14.0      Revision Date: 18.12.2024      SDS Number: 27553-00027      Date of last issue: 03.12.2024  
Date of first issue: 03.11.2014

H351 Suspected of causing cancer.  
H360FD May damage fertility. May damage the unborn child.  
H373 May cause damage to organs (Bone marrow, thymus gland, Lymph nodes, spleen) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P301 + P312 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.  
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.

**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.    | Classification  | Concentration (% w/w) |
|-----------------|------------|---|-----------------------|
| Citric acid     | 77-92-9    | Eye Irrit., 2A<br>STOT SE, 3  | >= 10 -< 20           |
| Sodium chloride | 7647-14-5  | Acute Tox. (Oral), 5  | >= 10 -< 20           |
| Temozolomide    | 85622-93-1 | Acute Tox. (Oral), 4<br>Muta., 2<br>Carc., 2<br>Repr., 1B<br>STOT RE,<br>(Oral)(Bone marrow,<br>thymus gland, Lymph<br>nodes, spleen) , 1 | >= 5 -< 10            |

**SECTION 4. FIRST AID MEASURES**

## Temozolomide Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

|   |   |  |
|---|---|--|
| General advice  | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.   |
| If inhaled  | : | If inhaled, remove to fresh air.<br>Get medical attention.   |
| In case of skin contact                                     | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<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.  |
| Most important symptoms and effects, both acute and delayed | : | Contact with dust can cause mechanical irritation or drying of the skin.<br>May be 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>May cause 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<br>Chlorine compounds   |
| Specific extinguishing methods        | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.   |

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**SECTION 7. HANDLING AND STORAGE**

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.

## Temozolomide Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

- 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 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<br>(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 |

- 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.

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

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.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing.                    |

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

|   |   |  |
|---|---|--|
| Physical state                          | : | powder   |
| Color                                   | : | white  |
| Odor                                    | : | No data available                                      |
| Odor Threshold                          | : | No data available                                      |
| pH                                      | : | No data available                                      |
| Melting point/freezing point            | : | No data available                                      |
| Initial boiling point and boiling range | : | No data available                                      |
| Flash point                             | : | Not applicable   |
| Evaporation rate                        | : | Not applicable   |
| Flammability (solid, gas)               | : | May form explosive dust-air mixture during processing, |

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

---

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

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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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : Heat, flames and sparks.<br>Avoid dust formation.  |
| Incompatible materials             | : Oxidizing agents   |
| Hazardous decomposition products   | : No hazardous decomposition products are known.   |

## Temozolomide Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure :  
Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

|| May be harmful if swallowed.

**Product:**

|| Acute oral toxicity : Acute toxicity estimate: 3.586 mg/kg  
Method: Calculation method

**Components:****Citric acid:**

Acute oral toxicity : LD50 (Mouse): 5.400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

**Sodium chloride:**

Acute oral toxicity : LD50 (Rat): 3.550 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 42 mg/l  
Exposure time: 1 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

**Temozolomide:**

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

**Skin corrosion/irritation**

|| Not classified based on available information.

**Components:****Citric acid:**

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

**Sodium chloride:**

Species : Rabbit



## Temozolomide Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

---

Result : No skin irritation

**Serious eye damage/eye irritation**

|| Causes serious eye irritation.

**Components:****Citric acid:**

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

**Sodium chloride:**

|         |                     |
|---------|---------------------|
| Species | : Rabbit            |
| Result  | : No eye irritation |

**Respiratory or skin sensitization****Skin sensitization**

|| Not classified based on available information.

**Respiratory sensitization**

|| Not classified based on available information.

**Components:****Sodium chloride:**

|                    |                                 |
|--------------------|---------------------------------|
| Test Type          | : Local lymph node assay (LLNA) |
| Routes of exposure | : Skin contact                  |
| Species            | : Mouse                         |
| Result             | : negative                      |

**Temozolomide:**

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

**Germ cell mutagenicity**

|| Suspected of causing genetic defects.

**Components:****Citric acid:**

|                       |  |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|                       | Test Type: in vitro micronucleus test<br>Result: positive                |
|                       | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative   |

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

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

**Sodium chloride:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro)  
Result: positive

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

Test Type: Chromosome aberration test in vitro  
Result: positive

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Intraperitoneal injection  
Result: positive

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**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

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

---

**Carcinogenicity****||** Suspected of causing cancer.**Components:****Sodium chloride:**

|                   |   |           |
|-------------------|---|-----------|
| Species           | : | Rat       |
| Application Route | : | Ingestion |
| Exposure time     | : | 2 Years   |
| Result            | : | negative  |

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

|                              |   |   |
|------------------------------|---|---|
| Effects on fetal development | : | Test Type: One-generation reproduction toxicity study |
|                              |   | Species: Rat  |
|                              |   | Application Route: Ingestion                          |
|                              |   | Result: negative                                      |

**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. |
|------------------------------------|---|--|

**STOT-single exposure****||** Not classified based on available information.

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

---

**Components:****Citric acid:**

Assessment : May cause respiratory irritation.

**STOT-repeated exposure**

May cause 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:****Citric acid:**

Species : Rat  
NOAEL : 4.000 mg/kg  
LOAEL : 8.000 mg/kg  
Application Route : Ingestion  
Exposure time : 10 Days

**Sodium chloride:**

Species : Rat  
LOAEL : 2.533 mg/kg  
Application Route : Ingestion  
Exposure time : 2 y

**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

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

|                   |   |   |
|-------------------|---|---|
| LOAEL             | : | 6,3 mg/kg   |
| Application Route | : | Oral  |
| Exposure time     | : | 6 Months  |
| Target Organs     | : | Bone marrow, spleen, male reproductive organs, Gastrointestinal tract, thymus gland |

**Aspiration toxicity**

|| Not classified based on available information.

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

|           |   |   |
|-----------|---|---|
| Ingestion | : | Symptoms: Blood disorders, Nausea, Vomiting, Diarrhea, anorexia, Fatigue, hair loss |
|-----------|---|---|

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Citric acid:**

|                  |   |  |
|------------------|---|--|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l<br>Exposure time: 96 h |
|------------------|---|--|

|   |   |  |
|---|---|--|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 1.535 mg/l<br>Exposure time: 24 h |
|---|---|--|

**Sodium chloride:**

|                  |   |  |
|------------------|---|--|
| Toxicity to fish | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.840 mg/l<br>Exposure time: 96 h |
|------------------|---|--|

|   |   |  |
|---|---|--|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 4.136 mg/l<br>Exposure time: 48 h |
|---|---|--|

|                                  |   |   |
|----------------------------------|---|---|
| Toxicity to algae/aquatic plants | : | EC50: > 2.000 mg/l<br>Exposure time: 96 h |
|----------------------------------|---|---|

|                                     |   |  |
|-------------------------------------|---|--|
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 252 mg/l<br>Exposure time: 33 d |
|-------------------------------------|---|--|

|  |   |  |
|--|---|--|
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia pulex (Water flea)): 314 mg/l<br>Exposure time: 21 d |
|--|---|--|

|                            |   |                    |
|----------------------------|---|--------------------|
| Toxicity to microorganisms | : | EC10: > 1.000 mg/l |
|----------------------------|---|--------------------|

**Temozolomide:**

|                  |   |  |
|------------------|---|--|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
|------------------|---|--|

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

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

**Persistence and degradability****Components:****Citric acid:**

|                  |   |   |
|------------------|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 97 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301B |
|------------------|---|---|

**Temozolomide:**

|                    |   |   |
|--------------------|---|---|
| Biodegradability   | : | Result: rapidly degradable<br>Biodegradation: 83 %<br>Exposure time: 35 d |
| Stability in water | : | Degradation half life (DT50): < 1 d                                       |

**Bioaccumulative potential****Components:****Citric acid:**

|  |   |                |
|--|---|----------------|
| Partition coefficient: n-octanol/water | : | log Pow: -1,72 |
|--|---|----------------|

**Temozolomide:**

|  |   |               |
|--|---|---------------|
| Partition coefficient: n-octanol/water | : | log Pow: 1,35 |
|--|---|---------------|

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03.12.2024  |
| 14.0    | 18.12.2024     | 27553-00027 | Date of first issue: 03.11.2014 |

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

|                        |   |   |
|------------------------|---|---|
| Waste from residues    | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.   |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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****ANTT**

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**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

**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 | : | 18.12.2024 |
| Date format   | : | dd.mm.yyyy |

**Temozolomide Injection Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
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**Further information**

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.

**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for 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

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.