

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Temozolomide Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03/20/2023  |
| 11.1    | 09/26/2023     | 27582-00024 | Date of first issue: 11/03/2014 |

### SECTION 1. IDENTIFICATION

Product name : Temozolomide Injection Formulation

#### Manufacturer or supplier's details

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

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Acute toxicity (Oral) : Category 3  
Eye irritation : Category 2A  
Germ cell mutagenicity : Category 2  
Carcinogenicity : Category 2  
Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 1 (Bone marrow, thymus gland, Lymph nodes, spleen)  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
H301 Toxic 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.

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H372 Causes damage to organs (Bone marrow, thymus gland, Lymph nodes, spleen) through prolonged or repeated exposure if swallowed.

### Precautionary Statements

#### Prevention:

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

#### Response:

P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER. Rinse mouth.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P337 + P313 If eye irritation persists: Get medical attention.

#### Storage:

P405 Store locked up.

#### Disposal:

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

### Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name | CAS-No.    | Concentration (% w/w) |
|---------------|------------|-----------------------|
| Citric acid   | 77-92-9    | $\geq 10$ - $< 20$    |
| Temozolomide  | 85622-93-1 | $\geq 5$ - $< 10$     |

Actual concentration is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

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

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

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|                                                             |                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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>Call a physician or poison control center immediately.<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 | : Toxic 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.<br>Contact with dust can cause mechanical irritation or drying of the skin. |
| Protection of first-aiders                                  | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).                                                                                                                                                                      |
| Notes to physician                                          | : Treat symptomatically and supportively.                                                                                                                                                                                                                                                                                                          |

### SECTION 5. FIRE-FIGHTING MEASURES

|                                                |                                                                                                                                                                                                                                                   |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suitable extinguishing media                   | : Water spray<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.<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.                                                                                                                                            |

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

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

### SECTION 7. HANDLING AND STORAGE

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

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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

inert or nuisance dust      50 Million particles per cubic foot  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

15 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

15 Million particles per cubic foot  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

Dust, nuisance dust and particulates      10 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (Total dust)  
Basis: CAL PEL

5 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (respirable dust fraction)  
Basis: CAL PEL

| 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 cm <sup>2</sup>                       | Internal |

**Engineering measures** : 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

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technology designed to prevent leakage of compounds into the workplace.

### Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

|                |                     |
|----------------|---------------------|
| Appearance     | : powder            |
| Color          | : white             |
| Odor           | : No data available |
| Odor 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                                      | : | Not applicable                                                                  |
| Evaporation rate                                 | : | Not applicable                                                                  |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : | No data available                                                               |
| Upper explosion limit / Upper flammability limit | : | No data available                                                               |
| 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)<br>Water solubility              | : | soluble                                                                         |
| Partition coefficient: n-octanol/water           | : | Not applicable                                                                  |
| Autoignition temperature                         | : | No data available                                                               |
| Decomposition temperature                        | : | No data available                                                               |
| Viscosity<br>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 size                                    | : | No data available                                                               |

### 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.<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.                                                                             |

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Toxic if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 241.75 mg/kg  
Method: Calculation method

#### Components:

##### Citric acid:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

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

##### Temozolomide:

Acute oral toxicity : LD50 (Dog): 19 mg/kg

LD50 (Rat): 315 mg/kg

LD50 (Mouse): 205 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Citric acid:

Species : Rabbit

Method : OECD Test Guideline 404

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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                      |

### Respiratory or skin sensitization

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

#### Components:

##### **Temozolomide:**

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

### Germ cell mutagenicity

Suspected of causing genetic defects.

#### Components:

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

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

Test Type: in vitro micronucleus test  
Result: positive

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

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

##### **Temozolomide:**

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

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Test Type: Chromosome aberration test in vitro  
Test system: Human lymphocytes  
Result: positive

|                                     |                                                                                                                                      |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Germ cell mutagenicity - Assessment | : Positive results from in vitro mammalian mutagenicity assays, chemical structure activity relationship to known germ cell mutagens |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|

## Carcinogenicity

Suspected of causing cancer.

### 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 |
|------------------------------|---------------------------------------------------------|

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

|             |                                                                                                                          |
|-------------|--------------------------------------------------------------------------------------------------------------------------|
| <b>OSHA</b> | No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens. |
|-------------|--------------------------------------------------------------------------------------------------------------------------|

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

## 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<br>Species: Rat<br>Application Route: Oral |
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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.

#### Components:

##### Citric acid:

Assessment : May cause respiratory irritation.

### 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:

##### Citric acid:

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

##### Temozolomide:

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

Species : Rat, male  
NOAEL : 8.5 mg/kg  
LOAEL : 34 mg/kg  
Application Route : Oral

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

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Temozolomide:

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

#### Temozolomide:

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

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

|  |   |                                                                                      |
|--|---|--------------------------------------------------------------------------------------|
|  | : | NOEC (Pseudokirchneriella subcapitata (green algae)): 40 mg/l<br>Exposure time: 72 h |
|--|---|--------------------------------------------------------------------------------------|

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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

### Persistence and degradability

#### Components:

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

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

##### **Temozolomide:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 83 %  
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

## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

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

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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Temozolomide Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 03/20/2023  |
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### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

Not regulated as a dangerous good

##### IATA-DGR

Not regulated as a dangerous good

##### IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

#### Domestic regulation

##### 49 CFR

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

### SECTION 15. REGULATORY INFORMATION

#### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Combustible dust  
Acute toxicity (any route of exposure)  
Germ cell mutagenicity  
Carcinogenicity  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)  
Serious eye damage or eye irritation

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### US State Regulations

##### Pennsylvania Right To Know

|                                         |           |
|-----------------------------------------|-----------|
| D-mannitol                              | 69-65-8   |
| L-Threonine                             | 72-19-5   |
| Citric acid                             | 77-92-9   |
| Sodium chloride                         | 7647-14-5 |
| Polyethylene glycol sorbitan monooleate | 9005-65-6 |

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Temozolomide

85622-93-1

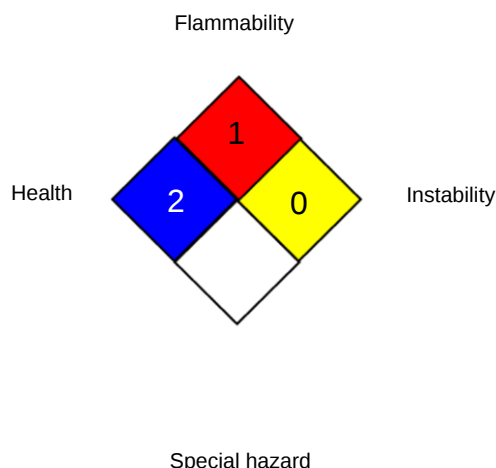
**The ingredients of this product are reported in the following inventories:**

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

### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

|                 |   |   |
|-----------------|---|---|
| HEALTH          | * | 3 |
| FLAMMABILITY    |   | 3 |
| PHYSICAL HAZARD |   | 0 |

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

|                |   |                                                                                         |
|----------------|---|-----------------------------------------------------------------------------------------|
| CAL PEL        | : | California permissible exposure limits for chemical contaminants (Title 8, Article 107) |
| OSHA Z-3       | : | USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts                      |
| CAL PEL / PEL  | : | Permissible exposure limit                                                              |
| OSHA Z-3 / TWA | : | 8-hour time weighted average                                                            |

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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

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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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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

Revision Date : 09/26/2023

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.

US / Z8