SAFETY DATA SHEET

Temozolomide Injection Formulation

Version 11.0 Revision Date: 03/20/2023 SDS Number: 27582-00023 Date of last issue: 10/01/2022 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 - repeated exposure (Oral): Category 1 (Bone marrow, thymus gland, Lymph nodes, spleen)

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.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Temozolomide</td>
<td>85622-93-1</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

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.

**In case of skin contact:**
In case of contact, immediately flush skin with soap and plenty
SAFETY DATA SHEET
Temozolomide Injection Formulation

Version: 11.0
Revision Date: 03/20/2023
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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.
Call a physician or poison control center immediately.
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.
Toxic 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. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- 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 (NOx)
- Metal oxides
- Chlorine compounds

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do 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
SAFETY DATA SHEET

Temozolomide Injection Formulation

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.

Materials to avoid:
Do not store with the following product types: Strong oxidizing agents.
SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS-Number</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
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<tbody>
<tr>
<td>Temozolomide</td>
<td>85622-93-1</td>
<td>TWA</td>
<td>0.1 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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 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

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

Water solubility: Soluble

Partition coefficient: n-octanol/water: Not applicable

Autoignition temperature: No data available

Decomposition temperature: No data available

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

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.
SAFETY DATA SHEET

Temozolomide Injection Formulation

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

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
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)
    - Result: negative
  - Test Type: in vitro micronucleus test
    - Result: positive
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative

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
**Carcinogenicity**
Suspected of causing cancer.

**Components:**

### Temozolomide

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Mammary gland</td>
</tr>
</tbody>
</table>

### Carcinogenicity - Assessment
Limited evidence of carcinogenicity in animal studies

- **IARC**
  - 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.

- **OSHA**
  - 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

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: One-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

### Temozolomide

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat, male</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Fertility: LOAEL: 8.5 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Embryo-fetal toxicity: LOAEL: 13 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: positive, Malformations were observed.</td>
<td></td>
</tr>
</tbody>
</table>

**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 pro-
longed 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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>4,000 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>8,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>10 Days</td>
</tr>
</tbody>
</table>

Temozolomide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, female</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>4 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>21 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Lymph nodes, thymus gland, Bone marrow, Reproductive organs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>8.5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>34 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Lymph nodes, thymus gland, Bone marrow, male reproductive organs, Gastrointestinal tract</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>2.5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>6.3 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
</tbody>
</table>
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
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1,535 mg/l
Exposure time: 24 h

**Temozolomide:**

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

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 90 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 40 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms: EC50: > 100 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Persistence and degradability

**Components:**

**Citric acid:**

**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.

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

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-mannitol</td>
<td>69-65-8</td>
</tr>
<tr>
<td>L-Threonine</td>
<td>72-19-5</td>
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<tr>
<td>Citric acid</td>
<td>77-92-9</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
</tr>
<tr>
<td>Polyethylene glycol sorbitan monooleate</td>
<td>9005-65-6</td>
</tr>
<tr>
<td>Temozolomide</td>
<td>85622-93-1</td>
</tr>
</tbody>
</table>

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

- AICS: not determined
- DSL: not determined
- IECSC: not determined
Further information

**NFPA 704:**

- **Flammability:** 1
- **Health:** 2
- **Special hazard:** 0
- **Instability:** 3

**HMIS® IV:**

- **HEALTH:** *
- **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

- **AICL:** 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 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
# SAFETY DATA SHEET

## Temozolomide Injection Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.0</td>
<td>03/20/2023</td>
<td>27582-00023</td>
<td>10/01/2022</td>
<td>11/03/2014</td>
</tr>
</tbody>
</table>

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 03/20/2023

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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US / Z8