

Temozolomide Injection Formulation

Version 10.1 Revision Date: 26.09.2023 SDS Number: 27548-00024 Date of last issue: 20.03.2023
Date of first issue: 03.11.2014

SECTION 1: IDENTIFICATION

Product name : Temozolomide Injection Formulation

Manufacturer or supplier's details

Company : MSD

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

Telephone : 1 800 033 461

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

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 3

Serious eye damage/eye irritation : Category 2A

Germ cell mutagenicity : Category 2

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B

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

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H301 Toxic if swallowed.
H319 Causes serious eye irritation.
H341 Suspected of causing genetic defects.

Temozolomide Injection Formulation

Version 10.1 Revision Date: 26.09.2023 SDS Number: 27548-00024 Date of last issue: 20.03.2023
 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.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

Contact with dust can cause mechanical irritation or drying of the skin.
 May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

SECTION 4. FIRST AID MEASURES

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

Temozolomide Injection Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 10.1 | 26.09.2023 | 27548-00024 | Date of first issue: 03.11.2014 |

When symptoms persist or in all cases of doubt seek medical advice.

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

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
Call a physician or poison control centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Toxic if swallowed.
Causes serious eye irritation.
Suspected of causing genetic defects.
Suspected of causing cancer.
May damage fertility. May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure if swallowed.
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. FIREFIGHTING 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 (NO_x)
Metal oxides
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: 20.03.2023 |
| 10.1 | 26.09.2023 | 27548-00024 | 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 firefighters : 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.
 Keep container closed when not in use.

Temozolomide Injection Formulation

Version 10.1 Revision Date: 26.09.2023 SDS Number: 27548-00024 Date of last issue: 20.03.2023
 Date of first issue: 03.11.2014

- Keep away from heat and sources of ignition.
 Take precautionary measures against static discharges.
 Do not eat, drink or smoke when using this product.
 Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
 When using do not eat, drink or smoke.
 Wash contaminated clothing before re-use.
 The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage** : Keep in properly labelled containers.
 Store locked up.
 Keep tightly closed.
 Store in accordance with the particular national regulations.
- Materials to avoid** : Do not store with the following product types:
 Explosives

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|--------------|------------|-------------------------------|--|----------|
| Temozolomide | 85622-93-1 | TWA | 0.1 ug/m3 (OEB 5) | Internal |
| | | Wipe limit | 1 µg/100 cm ² | 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 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

Temozolomide Injection Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 10.1 | 26.09.2023 | 27548-00024 | Date of first issue: 03.11.2014 |

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : white

Odour : No data available

Odour 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

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Temozolomide Injection Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 10.1 | 26.09.2023 | 27548-00024 | Date of first issue: 03.11.2014 |

| | | |
|--|---|--|
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | : | |
| Water solubility | : | soluble |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition 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 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. |
| Conditions to avoid | : | Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Toxic if swallowed.

Product:

Temozolomide Injection Formulation

Version 10.1 Revision Date: 26.09.2023 SDS Number: 27548-00024 Date of last issue: 20.03.2023
Date of first issue: 03.11.2014

Acute oral toxicity : Acute toxicity estimate: 243.59 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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Temozolomide Injection Formulation

Version 10.1 Revision Date: 26.09.2023 SDS Number: 27548-00024 Date of last issue: 20.03.2023
Date of first issue: 03.11.2014

Components:**Temozolomide:**

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

Chronic toxicity**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

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

Carcinogenicity

Suspected of causing cancer.

Components:**Temozolomide:**

Species : Rat
Application Route : Oral

Temozolomide Injection Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 10.1 | 26.09.2023 | 27548-00024 | Date of first issue: 03.11.2014 |

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 foetal 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 foetal development : Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Oral
 Embryo-foetal toxicity: LOAEL: 13 mg/kg body weight
 Result: positive, Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

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:

Exposure routes : Ingestion

Temozolomide Injection Formulation

Version 10.1 Revision Date: 26.09.2023 SDS Number: 27548-00024 Date of last issue: 20.03.2023
Date of first issue: 03.11.2014

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
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, Diarrhoea, anorexia, Fatigue, hair loss

Temozolomide Injection Formulation

Version 10.1 Revision Date: 26.09.2023 SDS Number: 27548-00024 Date of last issue: 20.03.2023
Date of first issue: 03.11.2014

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:**

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

Temozolomide:

Biodegradability : Result: rapidly degradable
Biodegradation: 83 %

Temozolomide Injection Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 10.1 | 26.09.2023 | 27548-00024 | Date of first issue: 03.11.2014 |

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 | : | Do not dispose of waste into sewer. Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

| | | |
|----------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |

IATA-DGR

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

Temozolomide Injection Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 10.1 | 26.09.2023 | 27548-00024 | Date of first issue: 03.11.2014 |

Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

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

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

Not applicable for product as supplied.

National Regulations

ADG

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

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

AICS : not determined
 DSL : not determined
 IECSC : not determined

Temozolomide Injection Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 10.1 | 26.09.2023 | 27548-00024 | Date of first issue: 03.11.2014 |

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date : 26.09.2023
Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>
Date format : dd.mm.yyyy

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

Temozolomide Injection Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 10.1 | 26.09.2023 | 27548-00024 | Date of first issue: 03.11.2014 |

intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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