

SAFETY DATA SHEET



Temozolomide Injection Formulation

Version
12.2

Revision Date:
14.04.2025

SDS Number:
27583-00030

Date of last issue: 23.01.2025
Date of first issue: 03.11.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Temozolomide Injection Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
117 16th Road
1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

| | |
|--|--|
| Eye irritation, Category 2 | H319: Causes serious eye irritation. |
| Germ cell mutagenicity, Category 2 | H341: Suspected of causing genetic defects. |
| Carcinogenicity, Category 2 | H351: Suspected of causing cancer. |
| Reproductive toxicity, Category 1B | H360FD: May damage fertility. May damage the unborn child. |
| Specific target organ toxicity - repeated exposure, Category 2 | H373: May cause damage to organs through prolonged or repeated exposure. |

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

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Hazard statements : 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.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Temozolomide

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------|---|---|--------------------------|
| Citric acid | 77-92-9 201-069-1 607-750-00-3 | Eye Irrit. 2; H319 STOT SE 3; H335 | >= 10 - < 20 |
| Temozolomide | 85622-93-1 | Acute Tox. 4; H302 Muta. 2; H341 Carc. 2; H351 Repr. 1B; H360FD STOT RE 1; H372 (Bone marrow, thymus gland, Lymph nodes, | >= 1 - < 10 |

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| | | | |
|--|--|---------|--|
| | | spleen) | |
|--|--|---------|--|

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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

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

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

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

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

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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.

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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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

| | |
|-------------------------|---|
| 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. |
| 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. |

7.2 Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| Requirements for storage areas and containers | : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
|---|---|

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Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

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

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|-----------------|-----------|-----------------|----------------------------|---------------------|
| Sodium chloride | Workers | Inhalation | Long-term systemic effects | 2068,62 mg/m3 |
| | Workers | Inhalation | Acute systemic effects | 2068,62 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 295,52 mg/kg bw/day |
| | Workers | Skin contact | Acute systemic effects | 295,52 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 443,28 mg/m3 |
| | Consumers | Inhalation | Acute systemic effects | 443,28 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 126,65 mg/kg bw/day |
| | Consumers | Skin contact | Acute systemic effects | 126,65 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 126,65 mg/kg bw/day |
| | Consumers | Ingestion | Acute systemic effects | 126,65 mg/kg bw/day |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|------------|
| Temozolomide | Fresh water | 0,08 mg/l |
| | Marine water | 0,08 mg/l |
| Citric acid | Fresh water | 0,44 mg/l |
| | Marine water | 0,044 mg/l |

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| | | |
|-----------------|------------------------|------------------------------|
| | Sewage treatment plant | 1000 mg/l |
| | Fresh water sediment | 34,6 mg/kg dry weight (d.w.) |
| | Marine sediment | 3,46 mg/kg dry weight (d.w.) |
| | Soil | 33,1 mg/kg dry weight (d.w.) |
| Sodium chloride | Fresh water | 5 mg/l |
| | Sewage treatment plant | 500 mg/l |
| | Soil | 4,86 mg/kg dry weight (d.w.) |

8.2 Exposure controls**Engineering measures**

The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

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

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

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 (P)

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Date of first issue: 03.11.2014**SECTION 9: Physical and chemical properties****9.1 Information on basic 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 |
| 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. |

9.2 Other information

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Molecular weight : No data available

Particle size : No data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

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

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 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

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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
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Temozolomide:**

Test Type : Maximisation Test
Exposure routes : 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

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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
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

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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 through prolonged or repeated exposure.

Components:**Temozolomide:**

Exposure routes : 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 : thymus gland, Bone marrow, Reproductive organs, Lymph nodes

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| | | |
|-------------------|---|--|
| Species | : | Rat, male |
| NOAEL | : | 8,5 mg/kg |
| LOAEL | : | 34 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 6 Months |
| Target Organs | : | thymus gland, Bone marrow, male reproductive organs, Gastrointestinal tract, Lymph nodes |
| Species | : | Dog |
| NOAEL | : | 2,5 mg/kg |
| LOAEL | : | 6,3 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 6 Months |
| Target Organs | : | Bone marrow, spleen, male reproductive organs, Gastrointestinal tract, thymus gland |

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

SECTION 12: Ecological information**12.1 Toxicity****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 |

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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

12.2 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

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

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

Temozolomide:

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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects**Product:**

Endocrine disrupting potential : The substance/mixture does not contain components consid-

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ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

| | |
|------------------------|--|
| Product | : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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**14.1 UN number**

| | |
|------|-------------------------------------|
| ADN | : Not regulated as a dangerous good |
| ADR | : Not regulated as a dangerous good |
| RID | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

14.2 UN proper shipping name

| | |
|------|-------------------------------------|
| ADN | : Not regulated as a dangerous good |
| ADR | : Not regulated as a dangerous good |
| RID | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

14.3 Transport hazard class(es)

| | |
|------|-------------------------------------|
| ADN | : Not regulated as a dangerous good |
| ADR | : Not regulated as a dangerous good |
| RID | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

14.4 Packing group

| | |
|-----|-------------------------------------|
| ADN | : Not regulated as a dangerous good |
| ADR | : Not regulated as a dangerous good |

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| | | |
|-------------------------|---|-----------------------------------|
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA (Cargo) | : | Not regulated as a dangerous good |
| IATA (Passenger) | : | Not regulated as a dangerous good |

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

| | | |
|--------|---|--|
| H302 | : | Harmful if swallowed. |
| H319 | : | Causes serious eye irritation. |
| H335 | : | May cause respiratory 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 through prolonged or repeated exposure if swallowed. |

Full text of other abbreviations

| | | |
|------------|---|------------------------|
| Acute Tox. | : | Acute toxicity |
| Carc. | : | Carcinogenicity |
| Eye Irrit. | : | Eye irritation |
| Muta. | : | Germ cell mutagenicity |
| Repr. | : | Reproductive toxicity |

SAFETY DATA SHEET



Temozolomide Injection Formulation

Version 12.2 Revision Date: 14.04.2025 SDS Number: 27583-00030 Date of last issue: 23.01.2025 Date of first issue: 03.11.2014

STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

Further information

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/>

Classification of the mixture:

| | |
|--------------|--------|
| Eye Irrit. 2 | H319 |
| Muta. 2 | H341 |
| Carc. 2 | H351 |
| Repr. 1B | H360FD |
| STOT RE 2 | H373 |

Classification procedure:

| |
|--------------------|
| Calculation method |

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

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Version
12.2

Revision Date:
14.04.2025

SDS Number:
27583-00030

Date of last issue: 23.01.2025
Date of first issue: 03.11.2014

considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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