SAFETY DATA SHEET

Temozolomide Formulation

Version 5.10  Revision Date: 09/13/2019  SDS Number: 25449-00015  Date of last issue: 2019/04/24  Date of first issue: 2014/10/24

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Temozolomide Formulation

Manufacturer or supplier’s details
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral) : Category 2
Serious eye damage/eye irritation : Category 2
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 : H300 Fatal 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/ 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:

Important symptoms and outlines of the emergency assumed:
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temozolomide</td>
<td>85622-93-1</td>
<td>&gt;= 50 - &lt; 60</td>
<td></td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-608</td>
</tr>
<tr>
<td>(+)-Tartaric acid</td>
<td>87-69-4</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td>2-1456</td>
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<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td>1-548</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES
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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 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: Fatal 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. 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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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.

7. HANDLING AND STORAGE

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. 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. Take care to prevent spills, waste and minimize release to the...
Avoidance of contact: Oxidizing agents
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.

Storage
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:
   Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temozolomide</td>
<td>85622-93-1</td>
<td>TWA</td>
<td>0.1 ug/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>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures: Minimize workplace exposure concentrations.
   Apply measures to prevent dust explosions.
   Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
   If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
   Filter type: Particulates type
   Hand protection: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending
Eye protection: Wear the following personal protective equipment: Safety goggles
Skin and body protection: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance: powder
- Colour: off-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: No data available
- Evaporation rate: No data available
- 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: No data available
- Relative vapour density: No data available
- Relative density: No data available
- Density: 1 g/cm³
- Solubility(ies):
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Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : No data available
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

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.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Fatal if swallowed.

Product:
Acute oral toxicity : Acute toxicity estimate: 33.93 mg/kg
   Method: Calculation method

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

**Stearic acid:**
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 2 mg/l  
Exposure time: 1 h  
Test atmosphere: vapour  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**(+)-Tartaric acid:**
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**Silicon dioxide:**
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 2.08 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Stearic acid:**
Species : Rabbit  
Method : Patch Test 24 Hrs.  
Result : No skin irritation

**(+)-Tartaric acid:**
Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation
Silicon dioxide:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

**Stearic acid:**
Species: Rabbit
Result: No eye irritation

(+) - **Tartaric acid:**
Species: Bovine cornea
Method: OECD Test Guideline 437
Result: Irreversible effects on the eye

Silicon dioxide:
Species: Rabbit
Result: No eye irritation

**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

**Stearic acid:**
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

(+) - **Tartaric acid:**
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Germ cell mutagenicity
Suspected of causing genetic defects.

Components:

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

Stearic acid:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

(+) Tartaric acid:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

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

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative
Silicon dioxide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

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

Carcinogenicity
Suspected of causing cancer.

Components:

Temozolomide:
Species: Rat
Application Route: Oral
Exposure time: 6 Months
Result: positive
Target Organs: Mammary gland

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

Silicon dioxide:
Species: Rat
Application Route: Ingestion
Exposure time: 103 weeks
Result: negative

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

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.

Stearic acid:
Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

(+)-Tartaric acid:
Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

Silicon dioxide:
Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

STOT - single exposure
Not classified based on available information.

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

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:

Temozolomide:
Species : Rat, female
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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

Stearic acid:
Species: Rat
NOAEL: 1,000 mg/kg
Application Route: Ingestion
Exposure time: 42 Days
Method: OECD Test Guideline 422
Remarks: Based on data from similar materials

(+)-Tartaric acid:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

Silicon dioxide:
Species: Rat
NOAEL: 1.3 mg/m3
Application Route: inhalation (dust/mist/fume)
Exposure time: 13 Weeks

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
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

Stearic acid:
Toxicity to fish : LL50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 48 h
Method: DIN 38412

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 10 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : NOELR (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOELR (Daphnia magna (Water flea)): > 0.5 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211
  Remarks: Based on data from similar materials
  No toxicity at the limit of solubility

Toxicity to microorganisms:

- EC10 (Pseudomonas putida): 883 mg/l
  Exposure time: 18 h

(+)-Tartaric acid:

Toxicity to fish:

- LC50 (Danio rerio (zebra fish)): > 100 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): 93.313 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

- EC50 (Pseudokirchneriella subcapitata (green algae)): 51.404 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

  NOEC (Pseudokirchneriella subcapitata (green algae)): 3.125 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to microorganisms:

- EC50: > 1,000 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209

Silicon dioxide:

Toxicity to fish:

- LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
  Exposure time: 24 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

- EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials

  NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials
Persistence and degradability

**Components:**

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

**Stearic acid:**
- Biodegradability: Result: Readily biodegradable.
  - Biodegradation: 71%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301B

**(+)-Tartaric acid:**
- Biodegradability: Result: Readily biodegradable.
  - Biodegradation: 85%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 306

Bioaccumulative potential

**Components:**

**Temozolomide:**
- Partition coefficient: n-octanol/water: log Pow: 1.35

**Stearic acid:**
- Partition coefficient: n-octanol/water: log Pow: 8.23

**(+)-Tartaric acid:**
- Partition coefficient: n-octanol/water: log Pow: -1.91

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
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.

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

**Fire Service Law**
Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**
Not applicable

**Harmful Substances Required Permission for Manufacture**
Not applicable

**Substances Prevented From Impairment of Health**
Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**
Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-Methyl-4-oxo-3,4-dihydroimidazo[5,1-d][1,2,3,5]tetrazone-8-carboxamide</td>
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<td></td>
</tr>
</tbody>
</table>

**Substances Subject to be Notified Names**

**Article 57-2 (Enforcement Order Table 9)**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystalline silica</td>
<td>165</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>
Substances Subject to be Indicated Names

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystalline silica</td>
<td>165 ☐ 2</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Bulk transportation</td>
<td>Noxious liquid substance(Category Z)</td>
</tr>
<tr>
<td>Pack transportation</td>
<td>Not classified as marine pollutant</td>
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</table>

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

<p>| |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>AICS</td>
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</table>
## SAFETY DATA SHEET

### Temozolomide 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>
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<tr>
<td>5.10</td>
<td>09/13/2019</td>
<td>25449-00015</td>
<td>2019/04/24</td>
<td>2014/10/24</td>
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<table>
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<tr>
<th>DSL</th>
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<tbody>
<tr>
<td>IECSC</td>
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</table>

### 16. OTHER INFORMATION

**Further information**


Date format: yyyy/mm/dd

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **ACGIH / TWA**: 8-hour, time-weighted average

- **AICS** - Australian Inventory of Chemical Substances; **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; **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 mate-
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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