1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Temozolomide Formulation

Manufacturer or supplier's details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Highly Toxic

GHS Classification
Acute toxicity (Oral) : Category 2
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 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:**
P203 Obtain, read and follow all safety instructions before use.
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 + P316 + P330 IF SWALLOWED: Get emergency medical help immediately. 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.
P318 IF exposed or concerned, get medical advice.
P337 + P317 If eye irritation persists: Get medical help.

**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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Temozolomide</td>
<td>85622-93-1</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
</tr>
<tr>
<td>(+)-Tartaric acid</td>
<td>87-69-4</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

**If inhaled:**
If inhaled, remove to fresh air. Get medical attention.
In case of skin contact: In case of contact, immediately flush skin with soap and plenty 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
SAFETY DATA SHEET

Temozolomide Formulation

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

Environmental precautions:
Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures:
Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
Keep in properly 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.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<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 particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</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 on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

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).

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working
When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

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)**
  - **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: 33.92 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 402
Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

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

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

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
- Method: OECD Test Guideline 429
- Result: negative
- Remarks: Based on data from similar materials

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
SAFETY DATA SHEET

Temozolomide Formulation

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

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

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

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
NOAEL: 4 mg/kg
LOAEL: 21 mg/kg
Application Route: Oral
Exposure time: 6 Months
Target Organs: Lymph nodes, thymus gland, Bone marrow, Reproductive
SAFETY DATA SHEET

Temozolomide Formulation

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

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
### Toxicty to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Exposure</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td>NOEC</td>
<td>&gt; 10 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

### Toxicty to algae/aquatic plants

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Exposure</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>&gt; 90 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC</td>
<td>&gt; 10 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

### Toxicty to microorganisms

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Exposure</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>&gt; 100 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

### Stearic acid:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Exposure</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>LL50</td>
<td>&gt; 10,000 mg/l</td>
<td>48 h</td>
<td>DIN 38412</td>
</tr>
</tbody>
</table>

### Toxicty to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Exposure</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EL50</td>
<td>&gt; 10 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td>Based on data from similar materials; No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>NOELR</td>
<td>&gt; 0.5 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td>Based on data from similar materials; No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicty to algae/aquatic plants

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Exposure</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOELR</td>
<td>&gt; 10 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials; No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicty to microorganisms

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC10</td>
<td>883 mg/l</td>
<td>18 h</td>
</tr>
</tbody>
</table>

### Toxicty to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Exposure</th>
<th>Species</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOELR</td>
<td>&gt; 0.5 mg/l</td>
<td>21 d</td>
<td>Daphnia magna (Water flea)</td>
<td>OECD Test Guideline 211</td>
<td>Based on data from similar materials; No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>
(+) - Tartaric acid:

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>EC50/Danio rerio (zebra fish): &gt; 100 mg/l</th>
<th>Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50/Daphnia magna (Water flea): 93.313 mg/l</td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>EC50/Pseudokirchneriella subcapitata (green algae): 51.404 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>NOEC/Pseudokirchneriella subcapitata (green algae): 3.125 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>EC50: &gt; 1,000 mg/l</td>
<td>Exposure time: 3 h</td>
</tr>
</tbody>
</table>

**Persistence and degradability**

**Components:**

**Temozolomide:**

<table>
<thead>
<tr>
<th>Biodegradability:</th>
<th>Result: rapidly degradable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation:</td>
<td>83 %</td>
</tr>
<tr>
<td>Exposure time:</td>
<td>35 d</td>
</tr>
</tbody>
</table>

**Stearic acid:**

<table>
<thead>
<tr>
<th>Biodegradability:</th>
<th>Result: Readily biodegradable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation:</td>
<td>71 %</td>
</tr>
<tr>
<td>Exposure time:</td>
<td>28 d</td>
</tr>
</tbody>
</table>

**(+) - Tartaric acid:**

<table>
<thead>
<tr>
<th>Biodegradability:</th>
<th>Result: Readily biodegradable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation:</td>
<td>85 %</td>
</tr>
<tr>
<td>Exposure time:</td>
<td>28 d</td>
</tr>
</tbody>
</table>

**Bioaccumulative potential**

**Components:**

**Temozolomide:**
SAFETY DATA SHEET

Temozolomide Formulation

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

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.
If not otherwise specified: Dispose of as unused product.

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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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
16. OTHER INFORMATION

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

Date format:
dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average

AIIIC - 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 Civil Aviation Organization; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Air Transport Association; 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 Standardisation; 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 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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