SECTION 1. IDENTIFICATION

Product name: Temozolomide Formulation

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Combustible dust
Acute toxicity (Oral): Category 2
Eye irritation: Category 2A
Germ cell mutagenicity: Category 2
Carcinogenicity: Category 2
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure (Oral): Category 1 (Bone marrow, thymus gland, Lymph nodes, spleen)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temozolomide</td>
<td>85622-93-1</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>(+)-Tartaric acid</td>
<td>87-69-4</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

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

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

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

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

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

Most important symptoms and effects, both acute and delayed:
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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media:
None known.

Specific hazards during fire fighting:
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides
Nitrogen oxides (NOx)
Metal oxides

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

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

Temozolomide Formulation

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Date of first issue: 10/24/2014

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.

SECTION 7. HANDLING AND STORAGE

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

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

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Do not get in eyes.
- 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 environment.

Conditions for safe storage:
- Keep in properly labeled 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
  - Organic peroxides
  - Flammable liquids
SAFETY DATA SHEET
Temozolomide Formulation

SECTION 8. EXPOSURE CONTROLS/PERSOHAL PROTECTION

Ingredients 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 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1 µg/100 cm²</td>
<td>Internal</td>
</tr>
<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. Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

Personal protective equipment
Respiratory protection:
General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled
release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration 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 place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : off-white

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : 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
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Date of first issue: 10/24/2014

Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor 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
Autoignition 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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions:
May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

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

Incompatible materials
Oxidizing agents

Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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: vapor
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

**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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Temozolomide:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: negative

Stearic acid:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

(+)-Tartaric acid:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: negative

Germ cell mutagenicity
Suspected of causing genetic defects.

Components:

Temozolomide:
SAFETY DATA SHEET

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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

Carcinogenicity
Suspected of causing cancer.

Components:

Temozolomide:
Species: Rat
Application Route: Oral
**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>
</tr>
</thead>
<tbody>
<tr>
<td>7.4</td>
<td>09/13/2019</td>
<td>25460-00015</td>
<td>04/24/2019</td>
<td>10/24/2014</td>
</tr>
</tbody>
</table>

- **Exposure time**: 6 Months
- **Result**: 4 mg/kg body weight
- **Target Organs**: Mammary gland

**Carcinogenicity - Assessment**

- **IARC**: Limited evidence of carcinogenicity in animal studies

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**NTP**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

May damage fertility. May damage the unborn child.

**Components:**

**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 fetal development**
  - **Test Type**: Embryo-fetal development
  - **Species**: Rat
  - **Application Route**: Oral
  - **Embryo-fetal 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 fetal 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 fetal development: Test Type: Embryo-fetal 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:
Routes of exposure: Ingestion
Target Organs: Bone marrow, thymus gland, Lymph nodes, spleen
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Temozolomide:
Species: Rat, female
NOAEL: 4 mg/kg
LOAEL: 21 mg/kg
Application Route: Oral
Exposure time: 6 Months
Target Organs: Lymph nodes, thymus gland, Bone marrow, Reproductive organs

Species: Rat, male
NOAEL: 8.5 mg/kg
LOAEL: 34 mg/kg
Application Route: Oral
Exposure time: 6 Months
Target Organs: Lymph nodes, thymus gland, Bone marrow, male reproductive organs, Gastrointestinal tract

Species: Dog
NOAEL: 2.5 mg/kg
LOAEL: 6.3 mg/kg
Application Route: Oral
Exposure time: 6 Months
Target Organs: Bone marrow, spleen, male reproductive organs, Gastrointestinal tract, thymus gland
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 y

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Temozolomide:
Ingestion : Symptoms: Blood disorders, Nausea, Vomiting, Diarrhea, anorexia, Fatigue, hair loss

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

**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

**Other adverse effects**
No data available

**SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation
49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know
CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards:
- Combustible dust
- Acute toxicity (any route of exposure)
- Serious eye damage or eye irritation
- Germ cell mutagenicity
- Carcinogenicity
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

SARA 313:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations
Pennsylvania Right To Know
- Lactose: 63-42-3
- Temozolomide: 85622-93-1
- Starch, carboxymethyl ether, sodium salt: 9063-38-1
Stearic acid 57-11-4

The ingredients of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

<table>
<thead>
<tr>
<th>NFPA 704:</th>
<th>HMIS® IV:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>HEALTH * 3</td>
</tr>
<tr>
<td>Health</td>
<td>FLAMMABILITY 3</td>
</tr>
<tr>
<td>Instability</td>
<td>PHYSICAL HAZARD 0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average
- AICS: Australian Inventory of Chemical Substances; ASTM: American Society for the Testing of Materials; bw: Body weight; CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act; CMR: Carcinogen, Mutagen or Reproductive Toxicant; DIN: Standard of the German Institute for Standardisation; DOT: Department of Transportation; DSL: Domestic Substances List (Canada); ECx: Concentration associated with x% response; EHS: Extremely Hazardous Substance; ELx: Loading rate associated with x% response; EmS: Emergency Schedule; ENCS: Existing and New Chemical Substances (Japan); ErCx: Concentration associated with x% growth rate response; ERG: Emergency Response Guide; GHS: Globally Harmonized System; GLP: Good Laboratory Practice; HMB: Hazardous Materials Identification System; IARC: International Agency for Research on Cancer; IATA: International Air Transport Association; IBC: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50: Half maximal inhibitory concentration; ICAO: International Civil Aviation Organization; IECSC: Inventory of Existing Chemical Substances in China; IMDG: International Maritime Dangerous Goods; IMO: International Maritime Organization; ISHL: Industrial Safety and Health Law (Japan); ISO: International Organisation for Standardization; KECI: Korea Existing Chemicals Inventory; LC50: Lethal Concentration to 50 % of a test population; LD50: Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL: International Convention for the Prevention of Pollution from Ships; MSHA: Mine Safety and Health Administration; n.o.s. - Not Other-

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