

Temozolomide Formulation

Version 8.1 Revision Date: 26.09.2023 SDS Number: 25451-00022 Date of last issue: 20.03.2023
Date of first issue: 24.10.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Temozolomide Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone : +52 55 57284444
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com



Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Acute toxicity (Oral) : Category 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:**

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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 or doctor/ physician. 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.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|-------------------|------------|-----------------------|
| Temozolomide | 85622-93-1 | >= 50 -< 70 |
| Stearic acid | 57-11-4 | >= 1 -< 5 |
| (+)-Tartaric acid | 87-69-4 | >= 1 -< 3 |

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.

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|---|---|--|
| In case of eye contact | : | Wash clothing before reuse. Thoroughly clean shoes before reuse. 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 (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire fighting | : | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides Nitrogen oxides (NO _x) Metal oxides |
| 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. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

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| 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). |
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- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
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.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

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Materials to avoid : Do not store with the following product types:

- Strong oxidizing agents
- Self-reactive substances and mixtures
- Organic peroxides
- Flammable liquids
- Flammable solids
- Pyrophoric liquids
- Pyrophoric solids
- Self-heating substances and mixtures
- Substances and mixtures which in contact with water emit flammable gases
- Explosives
- Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|--------------|------------|--|--|-------------------|
| Temozolomide | 85622-93-1 | TWA | 0.1 ug/m ³ (OEB 5) | Internal |
| | | Wipe limit | 1 µg/100 cm ² | Internal |
| Stearic acid | 57-11-4 | VLE-PPT | 10 mg/m ³ | NOM-010-STPS-2014 |
| | | TWA (Inhalable particulate matter) | 10 mg/m ³ | ACGIH |
| | | TWA (Respirable particulate matter) | 3 mg/m ³ | ACGIH |

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

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

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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).

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 |
| 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/cm ³ |
| Solubility(ies) | : | |

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| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| 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:

| | | |
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| Acute oral toxicity | : | Acute toxicity estimate: 33.92 mg/kg Method: Calculation method |
|---------------------|---|--|

Components:

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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 (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

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(+)-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:**

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

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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
 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.

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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.

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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

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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 |

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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

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

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

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

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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**NOM-002-SCT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 26.09.2023
Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE- : Time weighted average limit value
PPT

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and

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Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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