SAFETY DATA SHEET
Carbidopa / Levodopa Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Carbidopa / Levodopa Formulation

Manufacturer or supplier’s details
Company name of supplier: Organon & Co.
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Emergency telephone: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral): Category 4
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure (Oral): Category 1 (Central nervous system)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H302 Harmful if swallowed.
H361d Suspected of damaging the unborn child.
H372 Causes damage to organs (Central nervous system) 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 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levodopa</td>
<td>59-92-7</td>
</tr>
<tr>
<td>Carbidopa</td>
<td>38821-49-7</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
</tbody>
</table>

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:
If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed:
If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed:
Harmful if swallowed.
Suspected of damaging 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.
Dust contact with the eyes can lead to mechanical irritation.

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 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
- 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

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.
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: Use only with adequate ventilation.

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

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage: Keep in properly labeled containers. Store locked up. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents. Organic peroxides. Explosives. Gases.

SECTION 8. EXPOSURE CONTROLS/PERSONAL 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>Levodopa</td>
<td>59-92-7</td>
<td>TWA</td>
<td>500 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Carbidopa</td>
<td>38821-49-7</td>
<td>TWA</td>
<td>2,000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Carbidopa / Levodopa Formulation

<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.</th>
</tr>
</thead>
</table>
| 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  
**Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.  
**Skin and body protection**: Work uniform or laboratory coat. |

| SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Appearance | powder |
| Color | No data available |
| Odor | odorless |
| 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
Flammability (solid, gas)
Flammability (liquids)
Upper explosion limit / Upper flammability limit
Lower explosion limit / Lower flammability limit
Vapor pressure
Relative vapor density
Relative density
Density
Solubility(ies)
Water solubility
Partition coefficient: n-octanol/water
Autoignition temperature
Decomposition temperature
Viscosity
Viscosity, dynamic
Viscosity, kinematic
Explosive properties
Oxidizing properties
Molecular weight
Particle size

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**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
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 1,952 mg/kg
Method: Calculation method

Components:

Levodopa:
Acute oral toxicity: LD50 (Rat): 1,780 mg/kg
LD50 (Mouse): 2,363 mg/kg

Carbidopa:
Acute oral toxicity: LD50 (Rat): 4,810 mg/kg
LD50 (Mouse): 1,750 mg/kg

Cellulose:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Starch:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Magnesium stearate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
SAFETY DATA SHEET

Carbidopa / Levodopa Formulation

Version 6.6  Revision Date: 10.10.2020  SDS Number: 50121-00016  Date of last issue: 23.03.2020  Date of first issue: 23.01.2015

Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg  Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

Carbidopa:
Species: Rabbit
Result: No skin irritation

Magnesium stearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Carbidopa:
Species: Rabbit
Result: Mild eye irritation

Starch:
Species: Rabbit
Result: No eye irritation

Magnesium stearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Levodopa:
Species: Guinea pig
Result: Not a skin sensitizer.
Carbidopa / Levodopa Formulation

Carbidopa:
Remarks: No data available

Starch:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Magnesium stearate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

Levodopa:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosomal aberration
Test system: mouse lymphoma cells
Result: equivocal
Test Type: Micronucleus test
Test system: Chinese hamster lung cells
Result: positive
Test Type: sister chromatid exchange assay
Test system: Chinese hamster lung cells
Result: positive

Carbidopa:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: positive
Test Type: In vitro mammalian cell gene mutation test
Result: positive

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Cellulose:
<table>
<thead>
<tr>
<th>Component</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative</td>
</tr>
<tr>
<td>Starch</td>
<td>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials</td>
<td>Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 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</td>
</tr>
</tbody>
</table>

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Levodopa:**
Species: Rat  Application Route: Oral  Exposure time: 2 Years  Result: negative

**Carbidopa:**
Species: Rat  Application Route: Oral  Exposure time: 96 weeks  135 mg/kg body weight  Result: negative

**Cellulose:**
Species: Rat  Application Route: Ingestion  Exposure time: 72 weeks
Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Levodopa:
Effects on fertility
Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 100 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on fetal development
Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 125 mg/kg body weight
Symptoms: Skeletal malformations., Visceral malformations.
Result: positive

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 10 mg/kg body weight

Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: LOAEL: 500 mg/kg body weight
Symptoms: Effects on fetal development.
Result: positive

Reproductive toxicity - Assessment
Some evidence of adverse effects on development, based on animal experiments.

Carbidopa:
Effects on fertility
Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 120 mg/kg body weight
Symptoms: Reduced body weight
Result: Animal testing did not show any effects on fertility.

Effects on fetal development
Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 120 mg/kg body weight
Result: No teratogenic effects.

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 120 mg/kg body weight
Result: No teratogenic effects.

**Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Magnesium stearate:**

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: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

**Components:**

**Levodopa:**

Routes of exposure : Oral  
Target Organs : Central nervous system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Levodopa:**

Species : Rat  
LOAEL : 100 mg/kg  
Application Route : Oral  
Exposure time : 106 Weeks  
Target Organs : Central nervous system
### Carbidopa / Levodopa Formulation

#### Symptoms
- **Species**: Monkey
- **LOAEL**: 100 mg/kg
- **Application Route**: Oral
- **Exposure time**: 22 Weeks
- **Target Organs**: Central nervous system

#### Carbidopa:
- **Species**: Rat
- **LOAEL**: 25 mg/kg
- **Application Route**: Oral
- **Exposure time**: 96 Weeks
- **Remarks**: No significant adverse effects were reported

- **Species**: Monkey
  - **NOAEL**: 135 mg/kg
  - **Application Route**: Oral
  - **Exposure time**: 1 y
  - **Remarks**: No significant adverse effects were reported

- **Species**: Dog
  - **NOAEL**: 5 mg/kg
  - **LOAEL**: 15 mg/kg
  - **Application Route**: Oral
  - **Exposure time**: 238 d
  - **Symptoms**: Diarrhea, Vomiting, Tremors

#### Cellulose:
- **Species**: Rat
  - **NOAEL**: >= 9,000 mg/kg
  - **Application Route**: Ingestion
  - **Exposure time**: 90 Days

#### Starch:
- **Species**: Rat
  - **NOAEL**: >= 2,000 mg/kg
  - **Application Route**: Skin contact
  - **Exposure time**: 28 Days
  - **Method**: OECD Test Guideline 410

#### Magnesium stearate:
- **Species**: Rat
  - **NOAEL**: > 100 mg/kg
  - **Application Route**: Ingestion
  - **Exposure time**: 90 Days
  - **Remarks**: Based on data from similar materials

#### Aspiration toxicity
Not classified based on available information.
Experience with human exposure

Components:

Levodopa:
Ingestion: Symptoms: Nausea, central nervous system effects, Drowsiness

Carbidopa:
Ingestion: Symptoms: involuntary movement

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Levodopa:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 16 mg/l
Exposure time: 48 h

Carbidopa:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 35.3 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Cellulose:
Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Magnesium stearate:
Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1
mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms: EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Persistence and degradability

Components:

**Cellulose:**
Biodegradability: Result: Readily biodegradable.

**Magnesium stearate:**
Biodegradability: Result: Not biodegradable.
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

**Levodopa:**
Partition coefficient: n-octanol/water: log Pow: -2.39

**Magnesium stearate:**
Partition coefficient: n-octanol/water: log Pow: > 4

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

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

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-PPT : Time weighted average limit value

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
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 Organization 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

Sources of key data used to compile the Material Safety Data Sheet


Revision Date : 10.10.2020

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.

MX / Z8