1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Carbidopa / Levodopa Formulation

Supplier’s company name, address and phone number
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
            Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
E-mail address : EHSSTEWARD@organon.com
Emergency telephone number : 215-631-6999

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Acute toxicity (Oral) : Category 4
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Central nervous system)
Short-term (acute) aquatic hazard : Category 3
Long-term (chronic) aquatic hazard : Category 3

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.
                   H412 Harmful to aquatic life with long lasting effects.

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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor 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 which do not result in classification
Important symptoms and outlines of the emergency assumed:
- 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levodopa</td>
<td>59-92-7</td>
<td>&gt;= 70 - &lt; 80</td>
<td>9-1555</td>
</tr>
<tr>
<td>Carbidopa</td>
<td>38821-49-7</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 1 - &lt; 10</td>
<td>8-98</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</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: 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.

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
Metal oxides

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

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (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 spills cannot be contained.

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

7. HANDLING AND STORAGE

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

Local/Total ventilation: 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.

Avoidance of contact
Hygiene measures: Oxidizing agents
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.
SAFETY DATA SHEET

Carbidopa / Levodopa Formulation

Version 4.1  Revision Date: 2020/10/10  SDS Number: 50119-00016  Date of last issue: 2020/03/23  Date of first issue: 2015/01/23

Storage
Conditions for safe storage: Keep in properly labelled 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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>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>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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: 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES
<table>
<thead>
<tr>
<th>Physical state</th>
<th>powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</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>Lower explosion limit and upper explosion limit / flammability limit</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>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition 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>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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Density and / or relative 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>Relative vapour density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics
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
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
SAFETY DATA SHEET
Carbidopa / Levodopa Formulation

Version: 4.1  Revision Date: 2020/10/10  SDS Number: 50119-00016  Date of last issue: 2020/03/23
Date of first issue: 2015/01/23

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
   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 sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Levodopa:
Species: Guinea pig
Result: Not a skin sensitizer.

Carbidopa:
Remarks: No data available

Starch:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: 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
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:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Starch:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Magnesium stearate:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials
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

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
Result: 135 mg/kg body weight

**Cellulose:**
Species: Rat
Application Route: Ingestion
Exposure time: 72 weeks
Result: negative

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

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

Species: Mouse
Application Route: Oral
Developmental Toxicity: LOAEL: 500 mg/kg body weight
Symptoms: Effects on foetal 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 foetal development: Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 120 mg/kg body weight
Result: No teratogenic effects

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 foetal 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 foetal development: Test Type: Embryo-foetal 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:

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

### Repeated dose toxicity

#### Components:

### Levodopa:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>106 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Salivation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>22 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
</tbody>
</table>

### Carbidopa:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>25 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>96 Weeks</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>135 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 yr</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>15 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>238 d</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Diarrhoea, Vomiting, Tremors</td>
</tr>
</tbody>
</table>

### Cellulose:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt;= 9,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

### 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

**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
  - 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
SAFETY DATA SHEET

Carbidopa / Levodopa Formulation

Version 4.1 Revision Date: 2020/10/10 SDS Number: 50119-00016 Date of last issue: 2020/03/23 Date of first issue: 2015/01/23

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 Annex II of MARPOL 73/78 and the IBC Code Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations
Fire Service Law Not applicable to dangerous materials / designated flammables.
Chemical Substance Control Law Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.
Industrial Safety and Health Law
Harmful Substances Prohibited from Manufacture Not applicable
Harmful Substances Required Permission for Manufacture Not applicable
SAFETY DATA SHEET

Carbidopa / Levodopa Formulation

<table>
<thead>
<tr>
<th>Substance Prevented From Impairment of Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
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</table>

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

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**
Not applicable

<table>
<thead>
<tr>
<th>Substances Subject to be Notified Names</th>
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<tbody>
<tr>
<td>Article 57-2 (Enforcement Order Table 9)</td>
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<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
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<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
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<td>Article 57 (Enforcement Order Article 18)</td>
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**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**
Not applicable

**Ordinance on Prevention of Lead Poisoning**
Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**
Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**
Not applicable

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

**Poisonous and Deleterious Substances Control Law**
Not applicable

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

**High Pressure Gas Safety Act**
Not applicable

**Explosive Control Law**
Not applicable

**Vessel Safety Law**
Not regulated as a dangerous good

**Aviation Law**
Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**
Bulk transportation : Not classified as noxious liquid substance
Pack transportation: Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

**Waste Disposal and Public Cleansing Law**
Industrial waste

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

### 16. OTHER INFORMATION

**Further information**

Date format: yyyy/mm/dd

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

Abbreviations:
- 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 Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-
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<th>Date of last issue:</th>
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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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