1. PRODUCT AND COMPANY IDENTIFICATION

- Chemical product name: Carbidopa / Levodopa Formulation
- Supplier's company name, address and phone number
  - Company name of supplier: MSD
  - Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
  - Telephone: 048-588-8411
  - E-mail address: EHSDATASTEWARD@msd.com
  - Emergency telephone number: 1-908-423-6000

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 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.

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. 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. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact and 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

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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
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<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
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</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>
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</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>
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<td>Lower explosion limit and upper explosion limit / flammability limit</td>
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<tr>
<td>Upper explosion limit / Upper flammability limit</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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<td>Flash point</td>
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<td>Decomposition temperature</td>
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<td>pH</td>
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<td>Evaporation rate</td>
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<tr>
<td>Auto-ignition temperature</td>
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<tr>
<td>Viscosity, kinematic</td>
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<tr>
<td>Solubility(ies)</td>
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<tr>
<td>Water solubility</td>
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<td>Partition coefficient: n-octanol/water</td>
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<tr>
<td>Vapour pressure</td>
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<tr>
<td>Density and / or relative density</td>
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</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
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
Carbidopa / Levodopa Formulation

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

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

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

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 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:**
- Exposure routes: 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
- Symptoms: Salivation

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

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

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

**Starch:**
SAFETY DATA SHEET

Carbidopa / Levodopa Formulation

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 |
| 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: \( \log \text{Pow} = -2.39 \)

**Magnesium stearate:**
- Partition coefficient: n-octanol/water: \( \log \text{Pow} > 4 \)
SAFETY DATA SHEET

Carbidopa / Levodopa 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>
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<tbody>
<tr>
<td>4.0</td>
<td>2020/03/23</td>
<td>50119-00015</td>
<td>2019/09/13</td>
<td>2015/01/23</td>
</tr>
</tbody>
</table>

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to 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
Substances Prevented From Impairment of Health
Not applicable

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

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
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<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
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</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
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<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
</tbody>
</table>

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**

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

**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; 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); ECox - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCxx - 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
The information provided in this Safety Data Sheet is correct to the best of our knowledge, inform-

ation 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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