SECTION 1. IDENTIFICATION

Product name: Carbidopa / Levodopa Formulation

Manufacturer or supplier’s details
Company name of supplier: Organon & Co.
Address: 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
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: [Symbol]

Signal Word: Danger

Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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 and face protection.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and 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.

SECTION 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>
</tr>
</thead>
<tbody>
<tr>
<td>Levodopa</td>
<td>59-92-7</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Carbidopa</td>
<td>38821-49-7</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

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

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

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

In case of eye contact : 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 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 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 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.

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.
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.

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>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Carbidopa / Levodopa Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>TWA (respirable fraction)</th>
<th>TWA (Total)</th>
<th>TWA (Total Dust)</th>
<th>TWA (Inhalable particulate matter)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>5 mg/m^3</td>
<td>10 mg/m^3</td>
<td>15 mg/m^3</td>
<td>10 mg/m^3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>5 mg/m^3</td>
<td></td>
<td></td>
<td>10 mg/m^3</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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection Material: Chemical-resistant gloves

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

Hygiene measures: Work uniform or laboratory coat. 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.

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: 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: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
Viscosity, dynamic: No data available
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
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**:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Magnesium stearate**:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

**Carbidopa**:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

**Starch**:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>
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:
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
<table>
<thead>
<tr>
<th>Component</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbidopa</td>
<td>Test Type: Bacterial reverse mutation assay (AMES) Result: positive</td>
<td>Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test Result: positive</td>
<td></td>
</tr>
<tr>
<td>Cellulose</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</td>
</tr>
<tr>
<td></td>
<td>Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials</td>
<td></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
Result: negative

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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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

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

Reproductive toxicity
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
SAFETY DATA SHEET

Carbidopa / Levodopa Formulation

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
Symptoms : Salivation

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
**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>
</thead>
<tbody>
<tr>
<td>8.6</td>
<td>10/10/2020</td>
<td>50125-00016</td>
<td>03/23/2020</td>
<td>01/23/2015</td>
</tr>
</tbody>
</table>

### 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

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

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

Carbidopa / Levodopa Formulation

Version                  SDS Number:  Date of last issue: 03/23/2020
8.6  10/10/2020           50125-00016        Date of first issue: 01/23/2015

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

SARA 311/312 Hazards  :  Combustible dust
                        :  Acute toxicity (any route of exposure)
                        :  Reproductive toxicity
                        :  Specific target organ toxicity (single or repeated exposure)

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

US State Regulations

Pennsylvania Right To Know

Levodopa  59-92-7
Carbidopa  38821-49-7
Hydroxypropyl cellulose  9004-64-2
Cellulose  9004-34-6
Starch  9005-25-8

California Prop. 65
WARNING: This product can expose you to chemicals including Quartz, which is/are known to
the State of California to cause cancer, and
Levodopa, which is/are known to the State of California to cause birth defects or other reproduc-
tive harm. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

Cellulose  9004-34-6
Starch  9005-25-8
Magnesium stearate  557-04-0

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

AICS  :  not determined
DSL  :  not determined
IECSC  :  not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET
Carbidopa / Levodopa Formulation

Version 8.6 Revision Date: 10/10/2020 SDS Number: 50125-00016 Date of last issue: 03/23/2020 Date of first issue: 01/23/2015

NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; TWA - Time Weighted Average.
SAFETY DATA SHEET

Carbidopa / Levodopa Formulation

Version: 8.6  Revision Date: 10/10/2020  SDS Number: 50125-00016  Date of last issue: 03/23/2020

Revision Date: 10/10/2020

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.