

## 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

---

**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, 33rd 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.

---

# 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

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 out- : Dust contact with the eyes can lead to mechanical irritation.  
lines of the emergency as- : Contact with dust can cause mechanical irritation or drying of  
sumed : the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name      | CAS-No.    | Concentration (% w/w) | ENCS No. |
|--------------------|------------|-----------------------|----------|
| Levodopa           | 59-92-7    | >= 70 - < 80          | 9-1555   |
| Carbidopa          | 38821-49-7 | >= 10 - < 20          |          |
| Cellulose          | 9004-34-6  | >= 1 - < 10           |          |
| Starch             | 9005-25-8  | >= 1 - < 10           | 8-98     |
| Magnesium stearate | 557-04-0   | >= 1 - < 10           | 2-611    |

## 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.

# 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

---

- 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 (CO<sub>2</sub>)  
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 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).

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



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

---

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

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

# 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

| Components         | CAS-No.    | Value type (Form of exposure)       | Control parameters / Permissible concentration | Basis    |
|--------------------|------------|-------------------------------------|--|----------|
| Levodopa           | 59-92-7    | TWA                                 | 500 µg/m <sup>3</sup> (OEB 2)                  | Internal |
| Carbidopa          | 38821-49-7 | TWA                                 | 2,000 µg/m <sup>3</sup> (OEB 1)                | Internal |
| Cellulose          | 9004-34-6  | TWA                                 | 10 mg/m <sup>3</sup>                           | ACGIH    |
| Starch             | 9005-25-8  | TWA                                 | 10 mg/m <sup>3</sup>                           | ACGIH    |
| Magnesium stearate | 557-04-0   | TWA (Inhalable particulate matter)  | 10 mg/m <sup>3</sup>                           | ACGIH    |
|                    |            | TWA (Respirable particulate matter) | 3 mg/m <sup>3</sup>                            | ACGIH    |

- 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

# 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

---

Physical state : powder

Colour : No data available

Odour : odourless

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity  
Viscosity, dynamic : No data available  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Density and / or relative density  
Relative density : No data available

Density : No data available

Relative vapour density : No data available

# 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

---

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

## 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



## Carbidopa / Levodopa Formulation

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

---

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 / Levodopa Formulation

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

---

Result: positive

**Carbidopa:**

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

Test Type: In vitro mammalian cell gene mutation test  
Result: positive

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

**Cellulose:**

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

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

---

Application Route : Oral  
 Exposure time : 2 Years  
 Result : negative

**Carbidopa:**

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

**Cellulose:**

Species : Rat  
 Application Route : Ingestion  
 Exposure time : 72 weeks  
 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

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

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

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

**Carbidopa:**

## Carbidopa / Levodopa Formulation

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

---

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.

## Carbidopa / Levodopa Formulation

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

---

**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           | : | 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 yr   |
| 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          | : | Diarrhoea, Vomiting, Tremors |

**Cellulose:**

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

**Starch:**

## Carbidopa / Levodopa Formulation

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

---

|                   |   |                         |
|-------------------|---|-------------------------|
| 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<br>Exposure time: 48 h |
|---|---|---|

**Carbidopa:**

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

**Cellulose:**

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

**Magnesium stearate:**

|                  |   |  |
|------------------|---|--|
| Toxicity to fish | : | LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l<br>Exposure time: 48 h |
|------------------|---|--|

## Carbidopa / Levodopa Formulation

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

---

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  
 Method: Directive 67/548/EEC, Annex V, C.2.  
 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)): &gt; 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: &gt; 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

---

### **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

---



## 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

**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)

| Chemical name      | Number | Concentration (%) |
|--------------------|--------|-------------------|
| Magnesium stearate | 327    | >=1 - <10         |

**Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

| Chemical name      | Number |
|--------------------|--------|
| Magnesium stearate | 327    |

**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

## Carbidopa / Levodopa Formulation

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

---

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**

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIC - 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-

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



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

---

lative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

JP / EN