

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



Version 7.1      Revision Date: 30.09.2023      SDS Number: 50121-00022      Date of last issue: 04.04.2023  
Date of first issue: 23.01.2015

---

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Carbidopa / Levodopa Formulation

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : Avenida 16 de Septiembre No. 301  
Xaltocan - Xochimilco Mexico 16090  
Telephone : +52 55 57284444  
Emergency telephone : 1-215-631-6999  
E-mail address : EHSSTEWARD@organon.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

---

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

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

#### GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.  
H361d Suspected of damaging the unborn child.  
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



Version 7.1      Revision Date: 30.09.2023      SDS Number: 50121-00022      Date of last issue: 04.04.2023  
Date of first issue: 23.01.2015

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Levodopa	59-92-7	>= 70 -< 90
Carbidopa	38821-49-7	>= 10 -< 20
Cellulose	9004-34-6	>= 1 -< 5
Starch	9005-25-8	>= 1 -< 5
Magnesium stearate	557-04-0	>= 1 -< 5

### 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.

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
7.1	30.09.2023	50121-00022	Date of first issue: 23.01.2015

---

Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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 (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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

---

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



Version 7.1      Revision Date: 30.09.2023      SDS Number: 50121-00022      Date of last issue: 04.04.2023  
Date of first issue: 23.01.2015

certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

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

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



Version 7.1      Revision Date: 30.09.2023      SDS Number: 50121-00022      Date of last issue: 04.04.2023  
Date of first issue: 23.01.2015

Carbidopa	38821-49-7	TWA	2,000 µg/m <sup>3</sup> (OEB 1)	Internal
Cellulose	9004-34-6	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Starch	9005-25-8	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Magnesium stearate	557-04-0	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		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.

### 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

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation

Version 7.1      Revision Date: 30.09.2023      SDS Number: 50121-00022      Date of last issue: 04.04.2023  
Date of first issue: 23.01.2015

---

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 : No data available

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.

## Carbidopa / Levodopa Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
7.1	30.09.2023	50121-00022	Date of first issue: 23.01.2015

---

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

## Carbidopa / Levodopa Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
7.1	30.09.2023	50121-00022	Date of first issue: 23.01.2015

---

### **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 sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.



## Carbidopa / Levodopa Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
7.1	30.09.2023	50121-00022	Date of first issue: 23.01.2015

---

**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

Test Type: sister chromatid exchange assay  
Test system: Chinese hamster lung cells  
Result: positive

**Carbidopa:**

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

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

## Carbidopa / Levodopa Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
7.1	30.09.2023	50121-00022	Date of first issue: 23.01.2015

---

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

**Cellulose:**

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

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

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

**Starch:**

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

**Magnesium stearate:**

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

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:****Levodopa:**

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

**Carbidopa:**

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

## Carbidopa / Levodopa Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
7.1	30.09.2023	50121-00022	Date of first issue: 23.01.2015

---

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

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

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

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

**Carbidopa:**

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

Effects on fetal development : Test Type: Development  
 Species: Mouse  
 Application Route: Oral

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



Version 7.1      Revision Date: 30.09.2023      SDS Number: 50121-00022      Date of last issue: 04.04.2023  
Date of first issue: 23.01.2015

---

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.

## Carbidopa / Levodopa Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
7.1	30.09.2023	50121-00022	Date of first issue: 23.01.2015

---

**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

## Carbidopa / Levodopa Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
7.1	30.09.2023	50121-00022	Date of first issue: 23.01.2015

---

**Magnesium stearate:**

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

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Levodopa:**

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

**Carbidopa:**

Ingestion	:	Symptoms: involuntary movement
-----------	---	--------------------------------

---

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Levodopa:**

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

**Carbidopa:**

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

**Cellulose:**

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

**Magnesium stearate:**

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

Toxicity to daphnia and other aquatic invertebrates	:	EL50 (Daphnia magna (Water flea)): > 1 mg/l Exposure time: 47 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials
---	---	---

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



Version 7.1      Revision Date: 30.09.2023      SDS Number: 50121-00022      Date of last issue: 04.04.2023  
Date of first issue: 23.01.2015

---

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

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



Version 7.1      Revision Date: 30.09.2023      SDS Number: 50121-00022      Date of last issue: 04.04.2023  
Date of first issue: 23.01.2015

---

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

---

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

Not regulated as a dangerous good

##### IATA-DGR

Not regulated as a dangerous good

##### IMDG-Code

Not regulated as a dangerous good

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### Domestic regulation

##### NOM-002-SCT

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

---

### SECTION 15. REGULATORY INFORMATION

#### Safety, health and environmental regulations/legislation specific for the substance or mixture

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

### SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023  
Date format : dd.mm.yyyy

---



## Carbidopa / Levodopa Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
7.1	30.09.2023	50121-00022	Date of first issue: 23.01.2015

---

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
 NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
 NOM-010-STPS-2014 / VLE- : Time weighted average limit value  
 PPT

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8