

## Carbidopa / Levodopa Formulation

Version 5.0      Revision Date: 06.04.2024      SDS Number: 50124-00023      Date of last issue: 30.09.2023  
Date of first issue: 23.01.2015

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**Section 1: Identification**

**Product identifier** : Carbidopa / Levodopa Formulation

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

**Manufacturer or supplier's details**


Company : Organon & Co.  
Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302  
Telephone : +1-551-430-6000  
Emergency telephone number : +1-215-631-6999  
E-mail address : EHSSTEWARD@organon.com

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**Section 2: Hazard identification****Classification of the substance or mixture**

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

**GHS Label elements, including precautionary statements**

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

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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/ hearing 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**

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 -< 10
Starch	9005-25-8	>= 1 -< 10
Magnesium stearate	557-04-0	>= 1 -< 10

**Section 4: First-aid measures****Description of necessary 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.

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In case of eye contact : Thoroughly clean shoes before reuse.  
: 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**

Risks : 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).

**Indication of any immediate medical attention and special treatment needed**

Treatment : Treat symptomatically and supportively.

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**Section 5: Fire-fighting measures****Extinguishing media**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

**Special hazards arising from the substance or mixture**

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

**Special protective actions for fire-fighters**

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

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.

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**Section 6: Accidental release measures****Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions**

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**

Methods for 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.

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**Section 7: Handling and storage****Precautions for safe 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.

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Hygiene measures : Take care to prevent spills, waste and minimize release to the environment.  
: 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, including any incompatibilities**

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

**Section 8: Exposure controls/personal protection****Control parameters****Occupational Exposure Limits**

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	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Starch	9005-25-8	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Magnesium stearate	557-04-0	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

**Appropriate engineering** : Use feasible engineering controls to minimize exposure to

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**control measures**

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**Individual protection measures, such as personal protective equipment (PPE)**

- |                        |   |  |
|------------------------|---|--|
| Eye/face 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 protection        | : | Work uniform or laboratory coat.   |
| 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  |

**Section 9: Physical and chemical properties**

- |  |   |   |
|--|---|---|
| Appearance                                       | : | powder  |
| Colour   | : | No data available   |
| Odour  | : | odourless   |
| Odour 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   |

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Vapour pressure	:	No data available
Relative vapour 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
Auto-ignition 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 characteristics	:	
Particle size	:	No data available

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**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.

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**Section 11: Toxicological information**

Information on likely routes of exposure	:	Inhalation Skin contact
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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.



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**Components:****Carbidopa:**

Species : Rabbit  
Result : No skin irritation

**Magnesium stearate:**

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Carbidopa:**

Species : Rabbit  
Result : Mild eye irritation

**Starch:**

Species : Rabbit  
Result : No eye irritation

**Magnesium stearate:**

Species : Rabbit  
Result : No eye irritation  
Remarks : Based on data from similar materials

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

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

Species : Guinea pig  
Result : Not a skin sensitizer.

**Carbidopa:**

Remarks : No data available

**Starch:**

Test Type : Maximisation Test

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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
	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

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Genotoxicity in vivo	Result: negative
:	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
Result	: negative

**Cellulose:**

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

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**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:**

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

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Application Route: Oral  
 Developmental Toxicity: NOAEL: 120 mg/kg body weight  
 Result: No teratogenic effects

**Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

**Magnesium stearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 422  
 Result: negative  
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative  
 Remarks: Based on data from similar materials

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

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

Exposure routes : Oral  
 Target Organs : Central nervous system  
 Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Levodopa:**

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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:**

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

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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
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**Carbidopa:**

Ingestion	:	Symptoms: involuntary movement
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**Section 12: Ecological information****Toxicity****Components:****Levodopa:**

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

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

Biodegradability	: Result: Not biodegradable Remarks: Based on data from similar materials
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**Bioaccumulative potential****Components:****Levodopa:**

Partition coefficient: n-octanol/water	: log Pow: -2.39
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**Magnesium stearate:**

Partition coefficient: n-octanol/water	: log Pow: > 4
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**Mobility in soil**

No data available

**Other adverse effects**

No data available



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**Section 13: Disposal considerations****Disposal methods**

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

**Section 14: Transport information****International Regulations****UNRTDG**

- |                            |   |                |
|----------------------------|---|----------------|
| UN number                  | : | Not applicable |
| UN proper shipping name    | : | Not applicable |
| Transport hazard class(es) | : | Not applicable |
| Subsidiary risk            | : | Not applicable |
| Packing group              | : | Not applicable |
| Labels                     | : | Not applicable |
| Environmentally hazardous  | : | no             |

**IATA-DGR**

- |  |   |                |
|--|---|----------------|
| UN/ID No.                                | : | Not applicable |
| UN proper shipping name                  | : | Not applicable |
| Class                                    | : | Not applicable |
| Subsidiary risk                          | : | Not applicable |
| Packing group                            | : | Not applicable |
| Labels                                   | : | Not applicable |
| Packing instruction (cargo aircraft)     | : | Not applicable |
| Packing instruction (passenger aircraft) | : | Not applicable |

**IMDG-Code**

- |                         |   |                |
|-------------------------|---|----------------|
| UN number               | : | Not applicable |
| UN proper shipping name | : | Not applicable |
| Class                   | : | Not applicable |
| Subsidiary risk         | : | Not applicable |
| Packing group           | : | Not applicable |
| Labels                  | : | Not applicable |
| EmS Code                | : | Not applicable |
| Marine pollutant        | : | Not applicable |

**Transport in bulk according to IMO instruments**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

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**Section 15: Regulatory information****Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable  
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable  
Regulations

**The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

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**Section 16: Other information**

Revision Date : 06.04.2024

**Further information**

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

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

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
SG OEL : Singapore. Workplace Safety and Health (General Provisions)  
Regulations - First Schedule Permissible Exposure Limits of  
Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average  
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AllC - 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

# SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation



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5.0	06.04.2024	50124-00023	Date of first issue: 23.01.2015

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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; TECI - 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

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.

SG / EN