

# Carbidopa / Levodopa Formulation

Version Revision Date: SDS Number: Date of last issue: 10/27/2016 5.0 05/10/2017 50125-00006 Date of first issue: 01/23/2015

#### **SECTION 1. IDENTIFICATION**

Product name : Carbidopa / Levodopa Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road

Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

### **SECTION 2. HAZARDS IDENTIFICATION**

## GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

Acute toxicity (Oral) : Category 4

Reproductive toxicity : Category 2

Specific target organ

systemic toxicity - repeated

exposure (Oral)

Category 1 (Central nervous system)

## **GHS label elements**

Hazard pictograms :





Signal Word : Danger

Hazard Statements : If small particles are generated during further processing,

handling or by other means, may form combustible dust

concentrations in air. H302 Harmful if swallowed.

H361d Suspected of damaging the unborn child.

H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.



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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/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 dis-

posal plant.

### Other hazards

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

## **Hazardous ingredients**

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.



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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, 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

and effects, both acute delayed

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

Harmful if swallowed.

Suspected of damaging the unborn child.

Causes damage to organs through prolonged or repeated

exposure if swallowed.

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.

Notes to physician : Treat symptomatically and supportively.

## **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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**



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Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice and personal protective

equipment recommendations.

**Environmental precautions** Discharge into the environment must be avoided.

> Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable

container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## **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.

Do not breathe dust. Advice on safe handling

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage Keep in properly labeled containers.

Store locked up.

Store in accordance with the particular national regulations.

Materials to avoid Do not store with the following product types:

> Strong oxidizing agents Organic peroxides

**Explosives** 



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Gases

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
levodopa	59-92-7	TWA	2,000 μg/m³	Merck
Carbidopa	38821-49-7	TWA	2,000 μg/m³	Merck
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Res-	5 mg/m³	NIOSH REL
		pirable)		
		TWA (total)	10 mg/m³	NIOSH REL
		TWA (total	15 mg/m³	OSHA Z-1
		dust)		
		TWA (respir-	5 mg/m³	OSHA Z-1
		able fraction)		
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Res-	5 mg/m³	NIOSH REL
		pirable)		
		TWA (total)	10 mg/m³	NIOSH REL
		TWA (total	15 mg/m³	OSHA Z-1
		dust)		
		TWA (respir-	5 mg/m³	OSHA Z-1
11		able fraction)		
Magnesium stearate	557-04-0	TWA	10 mg/m³	ACGIH

## **Engineering measures**

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m3 - total dust, 5 mg/m3 - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m3 - respirable particles, 10 mg/m3 -

inhalable particles.

## Personal protective equipment

Respiratory protection

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.



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Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before

breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:

Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical

resistance data and an assessment of the local exposure

potential.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

Hygiene measures : Ensure that eye flushing systems and safety showers are

located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : No data available

Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available



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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

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.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Dust can form an explosive mixture in air. Can react with strong oxidizing agents.

Conditions to avoid : None known.



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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: 1,702 mg/kg

Method: Calculation method

**Ingredients:** 

levodopa:

Acute oral toxicity : LD50 (Rat): 1,500 - 2,000 mg/kg

LD50 (Mouse): 1,500 - 2,000 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

Assessment: The substance or mixture has no acute dermal

toxicity

Starch:

Acute oral toxicity : LD50 (Mouse): > 5,000 mg/kg

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,500 mg/kg

Assessment: The substance or mixture has no acute oral tox-

icity



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II

#### Skin corrosion/irritation

Not classified based on available information.

### **Ingredients:**

## Carbidopa:

Species: Rabbit

Result: No skin irritation

### Cellulose:

Result: No skin irritation

Remarks: Based on data from similar materials

### Serious eye damage/eye irritation

Not classified based on available information.

### **Ingredients:**

### Carbidopa:

Species: Rabbit

Result: Mild eye irritation

#### Cellulose:

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.

### Ingredients:

### Carbidopa:

Remarks: No data available

## Cellulose:

Test Type: Local lymph node assay (LLNA)

Routes of exposure: Skin contact

Species: Mouse

Method: OECD Test Guideline 429

Result: negative

Remarks: Based on data from similar materials

#### Magnesium stearate:

Routes of exposure: Skin contact

Result: negative



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### Germ cell mutagenicity

Not classified based on available information.

### **Ingredients:**

levodopa:

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

Result: negative

: Test Type: Chromosomal aberration Species: mouse lymphoma cells

Result: equivocal

: Test Type: Micronucleus test

Species: Chinese hamster lung cells

Result: positive

: Test Type: sister chromatid exchange assay

Species: 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

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

**Ingredients:** 

levodopa: Species: Rat



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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

IARC No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

OSHA No component of this product present at levels greater than or

equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or

equal to 0.1% is identified as a known or anticipated carcinogen

by NTP.

Reproductive toxicity

Suspected of damaging the unborn child.

**Ingredients:** 

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 - As- : Some evidence of adverse effects on development, based on



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sessment animal experiments.

Carbidopa:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 120 mg/kg body weight Symptoms: Reduced body weight

Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Test Type: Development

Species: Mouse

Application Route: Oral

Developmental Toxicity: NOAEL: 120 mg/kg body weight

Result: No teratogenic effects.

Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 120 mg/kg body weight

Result: No teratogenic effects.

## 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.

### Ingredients:

### levodopa:

Routes of exposure: Oral

Target Organs: Central nervous system

Assessment: Causes damage to organs through prolonged or repeated exposure.

## Repeated dose toxicity

### **Ingredients:**

### 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



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## 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: > 5,000 mg/kg Application Route: Ingestion Exposure time: 90 Days

Remarks: Based on data from similar materials

## Magnesium stearate:

Species: Rat

NOAEL: 5,000 mg/kg Application Route: Ingestion Exposure time: 3 Months

## **Aspiration toxicity**

Not classified based on available information.

#### **Experience with human exposure**

## **Ingredients:**

levodopa:

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

ness

Carbidopa:

Ingestion : Symptoms: involuntary movement



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### **SECTION 12. ECOLOGICAL INFORMATION**

## **Ecotoxicity**

### Ingredients:

levodopa:

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 16 mg/l

Exposure time: 48 h

Carbidopa:

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 35.3 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Cellulose:

LC50 (Cyprinus carpio (Carp)): > 100 mg/l Toxicity to fish

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Persistence and degradability

Ingredients:

Cellulose:

Biodegradability Result: Readily biodegradable.

Magnesium stearate:

Biodegradability : Result: Not biodegradable.

Bioaccumulative potential

**Ingredients:** 

levodopa:

Partition coefficient: n-

octanol/water

: log Pow: -2.39



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Mobility in soil

No data available

Other adverse effects

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14. TRANSPORT INFORMATION**

#### International Regulations

**UNRTDG** 

Not regulated as a dangerous good

**IATA-DGR** 

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

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

Not applicable for product as supplied.

**Domestic regulation** 

**49 CFR** 

Not regulated as a dangerous good

### **SECTION 15. REGULATORY INFORMATION**

## **EPCRA - Emergency Planning and Community Right-to-Know**

## **CERCLA Reportable Quantity**

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

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Fire Hazard

Acute Health Hazard Chronic Health Hazard



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SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

## **US State Regulations**

## Pennsylvania Right To Know

 levodopa
 59-92-7

 Carbidopa
 38821-49-7

 Hydroxypropyl cellulose
 9004-64-2

 Cellulose
 9004-34-6

 Starch
 9005-25-8

## California Prop. 65

WARNING! This product contains a chemical known in the State of California to cause cancer.

Quartz 14808-60-7

WARNING: This product contains a chemical known in the State of California to cause birth defects or other reproductive harm.

levodopa 59-92-7

## **California Permissible Exposure Limits for Chemical Contaminants**

 Cellulose
 9004-34-6

 Starch
 9005-25-8

 Magnesium stearate
 557-04-0

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

AICS : not determined

DSL : not determined

IECSC : not determined



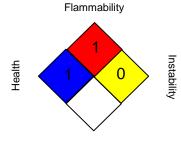
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#### **SECTION 16. OTHER INFORMATION**

#### **Further information**

#### NFPA:



Special hazard.

#### HMIS® IV:



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

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

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

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials: bw - Body weight: CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals: OECD - Organization for Economic Co-operation and Development; OPPTS - Office



# Carbidopa / Levodopa Formulation

Version Revision Date: SDS Number: Date of last issue: 10/27/2016 5.0 05/10/2017 50125-00006 Date of first issue: 01/23/2015

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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

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 Agen-

cy, http://echa.europa.eu/

Revision Date : 05/10/2017

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

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