

Version 5.2	Revision Date: 06.04.2024		S Number: 07-00023	Date of last issue: 30.09.2023 Date of first issue: 23.01.2015
	1: IDENTIFICATION			
Produ	uct name	:	Carbidopa / Levo	odopa Formulation
Manı	facturer or supplier's d	letai	ls	
Comp	bany	:	Organon & Co.	
Addre	ess	:	30 Hudson Stree Jersey City, New	t, 33nd floor Jersey, U.S.A 07302
Telep	hone	:	+1-551-430-6000	)
Emer	gency telephone number	· :	+1-215-631-6999	)
E-ma	il address	:	EHSSTEWARD	@organon.com
Reco	mmended use of the ch	nem	ical and restriction	ons on use
Reco	mmended use	:	Pharmaceutical	
Restr	ictions on use	:	Not applicable	
SECTION	2. HAZARDS IDENTIFIC	САТ	ION	
GHS	Classification			
Acute	e toxicity (Oral)	•	Category 4	

GHS Classification		
Acute toxicity (Oral)	:	Category 4
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Central nervous system)
GHS label elements		
Hazard pictograms	:	
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	:	<b>Prevention:</b> P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood.



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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 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.

Mixture

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

:

Substance / Mixture

Chemical name	CAS-No.	Concentration (% w/w)
Levodopa	59-92-7	>= 60 -<= 100
Carbidopa	38821-49-7	>= 10 -< 30
Cellulose	9004-34-6	< 10
Starch	9005-25-8	< 10
Magnesium stearate	557-04-0	< 10

#### **SECTION 4. FIRST AID MEASURES**

General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	<ul> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>
In case of eye contact	: If in eyes, rinse well with water.



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lf swa	allowed	:	If swallowed, DO Get medical atter Rinse mouth thor	ntion if irritation develops and persists. NOT induce vomiting. ntion. oughly with water. ing by mouth to an unconscious person.
	important symptoms effects, both acute and red	:	Harmful if swallov Suspected of dan Causes damage exposure if swallo	ved. naging the unborn child. to organs through prolonged or repeated
Prote	ection of first-aiders	:	First Aid respond and use the record	the eyes can lead to mechanical irritation. ers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8).
Notes	s to physician	:	•	ically and supportively.
SECTION	5. FIREFIGHTING MEA	SU	RES	
Suita	ble extinguishing media	:	Water spray	foom

		Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire- fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion 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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective 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.



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Methods and materials for : containment and cleaning up		Sweep up or vacuum up spillage and collect in suitable tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surf with compressed air). Dust deposits should not be allowed to accumulate on es, as these may form an explosive mixture if they are leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and posal of this material, as well as those materials and its employed in the cleanup of releases. You will need to of mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regi certain local or national requirements.		
SECTION	7. HANDLING AND ST	OR/	AGE	
Techn	ical measures	:	causing an explos	precautions, such as electrical grounding
	Total ventilation on safe handling	:	Use only with ade Do not breathe du Do not swallow. Avoid contact with	quate ventilation. st.

- 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 1 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 labelled containers. 1 Store locked up. Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:



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Strong oxidizing agents

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Levodopa	59-92-7	TWA	500 µg/m3 (OEB	Internal
			2)	
Carbidopa	38821-49-7	TWA	2,000 µg/m3	Internal
-			(OEB 1)	
Cellulose	9004-34-6	TWA	10 mg/m3	AU OEL
		TWA	10 mg/m3	ACGIH
Starch	9005-25-8	TWA	10 mg/m3	AU OEL
		TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	TWA	10 mg/m3	AU OEL
		TWA (Inhal-	10 mg/m3	ACGIH
		able particu-	_	
		late matter)		
		TWA (Res-	3 mg/m3	ACGIH
		pirable par-		
		ticulate mat-		
		ter)		

#### Components with workplace control parameters

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 equipm	ent	
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended 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



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Cold	Sur		No data available	2
Odo			odourless	
	our Threshold		No data available	<b>、</b>
		•		
pН	· · · · · · · · · · · · · · · · · · ·	:	No data available	
	ing point/freezing point	:	No data available	
Initia rang	al boiling point and boiling ge	:	No data available	9
Flas	h point	:	No data available	9
Eva	poration rate	:	No data available	9
Flan	nmability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- ans.
Flan	nmability (liquids)	:	No data available	9
	er explosion limit / Upper mability limit	:	No data available	
	er explosion limit / Lower mability limit	:	No data available	9
Vap	our pressure	:	No data available	2
Rela	ative vapour density	:	No data available	9
Rela	ative density	:	No data available	9
Den	sity	:	No data available	9
	ıbility(ies) Vater solubility	:	No data available	9
	ition coefficient: n-	:	No data available	)
	nol/water p-ignition temperature	:	No data available	2
Dec	omposition temperature	:	No data available	2
	osity /iscosity, dynamic	:	No data available	9
١	/iscosity, kinematic	:	No data available	9
Exp	losive properties	:	Not explosive	



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Oxidiz	ing properties	:	The substance	or mixture is not classified as oxidizing.
	ular weight		No data availat	-
	Ū			
	Particle characteristics Particle size		No data availat	ble
ECTION	10. STABILITY AND RE	EAC	ΤΙVITY	
React		:		s a reactivity hazard.
	ical stability bility of hazardous reac-	:		ormal conditions. sive dust-air mixture during processing, han
tions			dling or other n	neans. strong oxidizing agents.
Condi	tions to avoid		Heat, flames a	
		•	Avoid dust form	nation.
	patible materials dous decomposition cts	:	Oxidizing agen No hazardous	ts decomposition products are known.
ECTION	11. TOXICOLOGICAL I	NFC	ORMATION	
Expos	sure routes	:	Inhalation	
Expos	sure routes	:	Skin contact	
Expos	sure routes	:		
	sure routes • toxicity	:	Skin contact Ingestion	
Acute		:	Skin contact Ingestion	
<b>Acute</b> Harmf <u>Produ</u>	<b>toxicity</b> iul if swallowed. <u>uct:</u>	:	Skin contact Ingestion Eye contact	
<b>Acute</b> Harmf <u>Produ</u>	<b>toxicity</b> ful if swallowed.	:	Skin contact Ingestion Eye contact	stimate: 1,952 mg/kg ation method
<b>Acute</b> Harmf <u>Produ</u> Acute	<b>toxicity</b> iul if swallowed. <u>uct:</u>	:	Skin contact Ingestion Eye contact Acute toxicity es	
<b>Acute</b> Harmf <u>Produ</u> Acute	e toxicity ful if swallowed. <u>Ict:</u> oral toxicity ponents:	:	Skin contact Ingestion Eye contact Acute toxicity es	
Acute Harmf <u>Produ</u> Acute <u>Comp</u> Levoc	e toxicity ful if swallowed. <u>Ict:</u> oral toxicity ponents:	:	Skin contact Ingestion Eye contact Acute toxicity es	ation method
Acute Harmf <u>Produ</u> Acute <u>Comp</u> Levoc	e toxicity ful if swallowed. <u>uct:</u> oral toxicity ponents: dopa:	:	Skin contact Ingestion Eye contact Acute toxicity es Method: Calcula	ation method 30 mg/kg
Acute Harmf <u>Produ</u> Acute <u>Comp</u> Levoc Acute	e toxicity ful if swallowed. <u>uct:</u> oral toxicity <u>conents:</u> dopa: oral toxicity	:	Skin contact Ingestion Eye contact Acute toxicity es Method: Calcula	ation method 30 mg/kg
Acute Harmf <u>Produ</u> Acute Comp Levoc Acute	e toxicity ful if swallowed. <u>uct:</u> oral toxicity <u>conents:</u> dopa: oral toxicity	:	Skin contact Ingestion Eye contact Acute toxicity es Method: Calcula	ation method 30 mg/kg 2,363 mg/kg



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Cellu	lose:				
	oral toxicity	:	LD50 (Rat): >	5,000 mg/kg	
Acute	inhalation toxicity	:	LC50 (Rat): > Exposure time Test atmosphe	:4 h	
Acute	dermal toxicity	:	LD50 (Rabbit)	: > 2,000 mg/kg	
Starc	h:				
Acute	oral toxicity	:	LD50 (Rat): >	5,000 mg/kg	
Acute	dermal toxicity	:	LD50 (Rabbit)	: > 2,000 mg/kg	
Magn	esium stearate:				
Acute	oral toxicity	:	Assessment: T	2,000 mg/kg D Test Guideline 423 The substance or mixture has no acute oral to ed on data from similar materials	
Acute	Acute dermal toxicity		LD50 (Rabbit): > 2,000 mg/kg Remarks: Based on data from similar materials		
	corrosion/irritation	- !! -  -  -			
	assified based on ava conents:	allable	information.		
	dopa:				
Speci Resul	es	:	Rabbit No skin irritatio	on	
Magn	esium stearate:				
Speci		:	Rabbit		
Resul Rema		:	No skin irritatio Based on data	on from similar materials	
Serio	us eye damage/eye	irritati	on		
	assified based on ava				
<u>Comp</u>	oonents:				
	dopa:				
Speci	es	•	Rabbit		



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Starc	.h.			
Speci			Rabbit	
Resu		:	No eye irritatio	n
Magr	nesium stearate:			
Spec		:	Rabbit	
Resu		:	No eye irritatio	
Rema	arks	:	Based on data	from similar materials
Resp	iratory or skin sensi	itisatio	on	
-	sensitisation lassified based on ava	ailahlo	information	
-	<b>iratory sensitisation</b> lassified based on avai		information.	
<u>Com</u>	ponents:			
Levo	dopa:			
Speci Resu		:	Guinea pig Not a skin sen	sitizer.
Carb	idopa:			
Rema	arks	:	No data availa	ble
Starc	:h:			
Test		:	Maximisation 7	est
	sure routes	:	Skin contact	
Speci Resu		:	Guinea pig negative	
Magr	nesium stearate:			
Test	Туре	:	Maximisation 7	est
Expo	sure routes	:	Skin contact	
Speci		:	Guinea pig	
Metho Resu		÷	OECD Test Gu negative	lideline 406
Rema		:		from similar materials
Chro	nic toxicity			
Germ	n cell mutagenicity			
Not c	lassified based on ava	ailable	information.	
<u>Com</u>	ponents:			
	dopa:			
Geno	toxicity in vitro	:	Test Type: Bad	cterial reverse mutation assay (AMES)



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				Result: negative	
				-	nosomal aberration
					use lymphoma cells
				Test Type: Micro Test system: Chin Result: positive	nucleus test nese hamster lung cells
					chromatid exchange assay nese hamster lung cells
Ca	arbid	opa:			
		oxicity in vitro	:	Test Type: Bacte Result: positive	rial reverse mutation assay (AMES)
				Test Type: In vitro Result: positive	o mammalian cell gene mutation test
G	enoto	oxicity in vivo	:	Test Type: Micro Species: Mouse Application Route Result: negative	
Ce	ellulo	ose:			
G	enoto	oxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
				Test Type: In vitro Result: negative	o mammalian cell gene mutation test
G	enoto	oxicity in vivo	:	Test Type: Mamr cytogenetic assay Species: Mouse Application Route Result: negative	
St	tarch	:			
G	enoto	oxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
M	agne	sium stearate:			
	-	oxicity in vitro	:	Result: negative	o mammalian cell gene mutation test on data from similar materials
				Test Type: Chron	nosome aberration test in vitro



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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 Application Route Exposure time Result	: :	Rat Oral 2 Years negative
Carbidopa:		
Species Application Route Exposure time Result		Rat Oral 96 weeks 135 mg/kg body weight negative
Cellulose:		
Species Application Route Exposure time Result	:	Rat Ingestion 72 weeks negative
Reproductive toxicity Suspected of damaging the unl	bor	n 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 develop- ment	:	Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 125 mg/kg body weight Symptoms: Skeletal malformations, Visceral malformations Result: positive



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				Test Type: Devel Species: Mouse Application Route	e: Oral oxicity: LOAEL: 10 mg/kg body weight opment
R	?enrod	luctive toxicity - As-		Symptoms: Effec Result: positive	ts on foetal development
	essme	•		animal experimer	•
	Carbid Effects	<b>opa:</b> on fertility	:	Symptoms: Redu	e: Oral 120 mg/kg body weight
	Effects nent	on foetal develop-	:	Test Type: Devel Species: Mouse Application Route Developmental T Result: No terato	e: Oral oxicity: NOAEL: 120 mg/kg body weight
				Test Type: Devel Species: Rabbit Application Route Developmental T Result: No terato	e: Oral oxicity: NOAEL: 120 mg/kg body weight
	Cellulo Effects	<b>ose:</b> on fertility	:	Test Type: One-g Species: Rat Application Route Result: negative	generation reproduction toxicity study e: Ingestion
	ffects nent	on foetal develop-	:	Test Type: Fertili Species: Rat Application Route Result: negative	ty/early embryonic development e: Ingestion
	-	sium stearate: on fertility	:		ined repeated dose toxicity study with the elopmental toxicity screening test



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Effects on foetal develop- ment		:	Result: negativ Remarks: Base Test Type: Em Species: Rat Application Ro Result: negativ	<ul> <li>Test Guideline 422</li> <li>e</li> <li>ed on data from similar materials</li> <li>bryo-foetal development</li> <li>ute: Ingestion</li> </ul>
	- single exposure			
Not cla	assified based on avai	ilable	information.	
	<b>.</b>		al nervous syste	em) through prolonged or repeated exposure
<u>Com</u> r	oonents:			
Targe	<b>dopa:</b> sure routes t Organs ssment	:	Oral Central nervou Causes damag exposure.	s system je to organs through prolonged or repeated
Repe	ated dose toxicity			
<u>Comr</u>	oonents:			
Expos	es L cation Route sure time t Organs		Rat 100 mg/kg Oral 106 Weeks Central nervou Salivation	s system
Expos		:	Monkey 100 mg/kg Oral 22 Weeks Central nervou	s system
	es L cation Route sure time	:	Rat 25 mg/kg Oral 96 Weeks No significant a	adverse effects were reported



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	EL cation Route sure time	<ul> <li>Monkey</li> <li>135 mg/kg</li> <li>Oral</li> <li>1 yr</li> <li>No significant adverse effects were reported</li> </ul>
	EL EL cation Route sure time	: Dog : 5 mg/kg : 15 mg/kg : Oral : 238 d : Diarrhoea, Vomiting, Tremors
	es	: Rat : >= 9,000 mg/kg : Ingestion : 90 Days
	es EL cation Route sure time	<ul> <li>Rat</li> <li>&gt;= 2,000 mg/kg</li> <li>Skin contact</li> <li>28 Days</li> <li>OECD Test Guideline 410</li> </ul>
Speci NOAE Applic	EL cation Route sure time	<ul> <li>Rat</li> <li>&gt; 100 mg/kg</li> <li>Ingestion</li> <li>90 Days</li> <li>Based on data from similar materials</li> </ul>
-	ation toxicity	able information.
Expe	rience with human e	oosure
<u>Comp</u>	oonents:	
Levoo Ingest		: Symptoms: Nausea, central nervous system effects, Drowsi- ness
<b>Carbi</b> Ingesi	dopa: tion	: Symptoms: involuntary movement



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### SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity		
Components:		
<b>Levodopa:</b> Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 16 mg/l Exposure time: 48 h
<b>Carbidopa:</b> 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 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



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		Test s	sure time: 16 h substance: Water Accommodated Fraction irks: Based on data from similar materials
			rks: Based on data from similar materials
Persi	stence and degrada	oility	
<u>Comp</u>	<u>ponents:</u>		
Cellu			
Biode	gradability	: Result	t: Readily biodegradable.
Magn	esium stearate:		
-	gradability		t: Not biodegradable ırks: Based on data from similar materials
Bioac	cumulative potentia	I	
<u>Comp</u>	oonents:		
Levo	dopa:		
	ion coefficient: n- ol/water	: log Po	ow: -2.39
Partiti	esium stearate: ion coefficient: n- ol/water	: log Pc	ow: > 4
Mobil	lity in soil		
No da	ata available		
	r <b>adverse effects</b> ata available		

### 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 han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

## International Regulations

UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable



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Packing group Labels Environmentally hazardous		: Not app : Not app : no		
UN/I Prop Clas Subs Pack Labe Pack aircr	sidiary risk king group els king instruction (cargo	<ul> <li>Not app</li> </ul>	blicable blicable blicable blicable blicable blicable	
UN r Prop Clas Subs Pack Labe EmS	sidiary risk king group	<ul> <li>Not app</li> </ul>	blicable blicable blicable blicable blicable blicable blicable	

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

Not applicable for product as supplied.

### **National Regulations**

ADG		
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable

### Special precautions for user

Not applicable

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

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

Therapeutic Goods (Poisons	:	No poison schedule number allocated (Please use the original
Standard) Instrument		publication to check for specific uses, specific conditions or
		threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements

: There is no applicable prohibition, authorisation and restricted use requirements, including for carcino-



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			gens referred to in Schedule 10 of the model WHS Act and Regula-tions.
The c	omponents of this pr	oduct are reported	I in the following inventories:
AICS		: not determine	ed
DSL		: not determine	ed
IECS	C	: not determine	ed

### SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information				
Revision Date Sources of key data used to compile the Safety Data Sheet	:	06.04.2024 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/		
Date format :		dd.mm.yyyy		
Full text of other abbreviations				
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)		
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Con- taminants.		
ACGIH / TWA	:	8-hour, time-weighted average		
AU OEL / TWA	:	Exposure standard - time weighted average		

AIIC - 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 Substanc-

## SAFETY DATA SHEET



## Carbidopa / Levodopa Formulation

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es; (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.

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