

Version 5.6	Revision Date: 10.10.2020	SDS Num 51049-000		Date of last issue: 23.03.2020 Date of first issue: 23.01.2015				
SECTION	SECTION 1. PRODUCT AND COMPANY IDENTIFICATION							
Prod	Product name		Carbidopa / Levodopa Formulation					
Man	ufacturer or supplier	s details						
Com	ipany	: Orgai	Organon & Co.					
Addr	Address		30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302					
Tele	phone	: 551-4	551-430-6000					
Eme	rgency telephone	: 215-6	215-631-6999					
E-ma	E-mail address		EHSSTEWARD@organon.com					
Reco	ommended use of the	chemical an	d restriction	s on use				
Reco	Recommended use		naceutical					
SECTION	SECTION 2. HAZARDS IDENTIFICATION							

GHS Classification Acute toxicity (Oral)	:	Category 4
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Central nervous system)
Short-term (acute) aquatic hazard	:	Category 3
Long-term (chronic) aquatic hazard	:	Category 3
GHS label elements Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H302 Harmful if swallowed. H361d Suspected of damaging the unborn child. H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed. H412 Harmful to aquatic life with long lasting effects.
Precautionary Statements	:	Prevention:



Version 5.6	Revision Date: 10.10.2020	SDS Number: 51049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015			
		P202 Do not and understo P260 Do not P264 Wash s P270 Do not P273 Avoid re	breathe dust. kin thoroughly after handling. eat, drink or smoke when using this product. elease to the environment. rotective gloves/ protective clothing/ eye protec-			
	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 Ic	ocked up.			
		e of contents/ container to an approved waste t.				
Othe	r hazards which do r	not result in classific	ation			
Conta	contact with the eyes act with dust can caus form explosive dust-ai	e mechanical irritation				
SECTION	3. COMPOSITION/IN	IFORMATION ON INC	GREDIENTS			
Subs	tance / Mixture	: Mixture				
Com	ponents					

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 medica advice. 	al
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 plen of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. 	nty



Version 5.6	Revision Date: 10.10.2020	SDS Number: 51049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015				
In case of eye contact If swallowed		: If in eyes, rinse Get medical at : If swallowed, I	Thoroughly clean shoes before reuse. If in eyes, rinse well with water. Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention.				
Most important symptoms and effects, both acute and delayed		Rinse mouth the Never give any Harmful if swa Suspected of Causes damage exposure if swa Contact with d	Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. 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.				
	ction of first-aiders to physician	 The skin. Dust contact with the eyes can lead to mechanical in First Aid responders should pay attention to self-prot and use the recommended personal protective equip when the potential for exposure exists (see section 8 Treat symptomatically and supportively. 					

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media Unsuitable extinguishing		Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical None known.
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 fire-fighters	:	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 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.



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
5.6	10.10.2020	51049-00016	Date of first issue: 23.01.2015
	ds and materials for nment and cleaning up	container for Avoid disper- with compres Dust deposit surfaces, as released into Local or nation disposal of the employed in determine with Sections 13	sal of dust in the air (i.e., clearing dust surfaces

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 Advice on safe handling		Use only with adequate ventilation. 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.
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 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
------------	---------	-------------------------------------	--	-------

_



Carbidopa / Levodopa Formulation

rsion	Revision Date: 10.10.2020		S Number: 49-00016		t issue: 23.03.2020 t issue: 23.01.2015		
Levoo	lopa	5	59-92-7	TWA	500 µg/m3 (OEB 2)	Internal	
Carbi	dopa	3	38821-49-7	TWA	2,000 µg/m3 (OEB 1)	Internal	
Cellul	ose	ç	9004-34-6	CMP	10 mg/m ³	AR OEL	
		F	Further informa	ation: Irritation			
				TWA	10 mg/m ³	ACGIH	
Starc	1		9005-25-8	CMP	10 mg/m ³	AR OEL	
			Further informatitie		lassifiable as a huma	in carcinogen,	
-				TWA	10 mg/m ³	ACGIH	
Magn	esium stearate	5	557-04-0	CMP	10 mg/m ³	AR OEL	
			Further informa	TWA	lassifiable as a huma 10 mg/m³	ACGIH	
				(Inhalable particulate matter)			
				TWA (Respirable particulate matter)	3 mg/m ³	ACGIH	
Engir	neering measures		compound. All engineering design and op	g controls shoul erated in accord	rols to minimize expo d be implemented by dance with GMP prin d the environment.	facility	
Perso	onal protective equip	ment					
Respi	ratory protection	:	exposure asse	essment demon I guidelines, use	tilation is not availabl strates exposures ou e respiratory protectio	tside the	
Hand	protection aterial		Chemical-resi				
Eye p	rotection		: 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				
	and body protection ne measures	:	 aerosols. Work uniform or laboratory coat. 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.



Version 5.6	Revision Date: 10.10.2020		S Number: 049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
SECTION	9. PHYSICAL AND CHI	ΞΜΙΟ		S
Арреа	arance	:	powder	
Color		:	No data available	9
Odor		:	odorless	
Odor	Threshold	:	No data available	9
рН		:	No data available	9
Meltin	g point/freezing point	:	No data available	9
Initial range	boiling point and boiling	:	No data available	9
Flash	point	:	No data available	9
Evapo	pration rate	:	No data available	9
Flamr	nability (solid, gas)	:	May form explosing the second	ive dust-air mixture during processing, means.
Flamr	nability (liquids)	:	No data available	9
	explosion limit / Upper ability limit	:	No data available	9
	r explosion limit / Lower ability limit	:	No data available	9
Vapor	pressure	:	No data available	9
Relati	ve vapor density	:	No data available	9
Relati	ve density	:	No data available	9
Densi	ty	:	No data available	9
	ility(ies) ater solubility	:	No data available	9
	on coefficient: n-	:	No data available	9
	ol/water gnition temperature	:	No data available	9
Decor	mposition temperature	:	No data available	9
Visco: Vis	sity scosity, dynamic	:	No data available	9
Vis	scosity, kinematic	:	No data available	9
Explo	sive properties	:	Not explosive	



Version 5.6	Revision Date: 10.10.2020		9S Number: 049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015			
Oxidizi	ng properties	:	The substance	or mixture is not classified as oxidizing.			
Molecu	Molecular weight		No data available				
Particle	e size	:	No data availal	ble			
SECTION 1	0. STABILITY AND R	EAC	TIVITY				
	rity cal stability ility of hazardous reac-	:	Stable under n May form explo handling or oth	as a reactivity hazard. ormal conditions. osive dust-air mixture during processing, er means. strong oxidizing agents.			
Conditi	ons to avoid	:	Heat, flames an Avoid dust forn				
	patible materials lous decomposition ts	:	Oxidizing agen				
SECTION 1	1. TOXICOLOGICAL	INFO	ORMATION				
Informa exposu	ation on likely routes of ire	:	Inhalation Skin contact Ingestion Eye contact				
	toxicity Il if swallowed.		-				
Produc	ct:						
Acute o	oral toxicity	:	Acute toxicity es Method: Calcula	stimate: 1.952 mg/kg ation method			
Compo	onents:						
Levod	opa:						
Acute of	oral toxicity	:	LD50 (Rat): 1.7	80 mg/kg			
			LD50 (Mouse):	2.363 mg/kg			
Carbid	•						
Acute of	oral toxicity	:	LD50 (Rat): 4.8	10 mg/kg			
			LD50 (Mouse):	1.750 mg/kg			
Cellulo				000			
Acute of	oral toxicity	:	LD50 (Rat): > 5	.000 mg/kg			
Acute i	nhalation toxicity	:	LC50 (Rat): > 5 Exposure time:				



rsion S	Revision Date: 10.10.2020	SDS Nun 51049-00		Date of last issue: 23.03.2020 Date of first issue: 23.01.2015		
		Test a	atmospher	e: dust/mist		
Acute	e dermal toxicity	: LD50	(Rabbit): :	> 2.000 mg/kg		
Starc	h:					
Acute	Acute oral toxicity		LD50 (Rat): > 5.000 mg/kg			
Acute	e dermal toxicity	: LD50	(Rabbit): :	> 2.000 mg/kg		
Magn	esium stearate:					
Acute	oral toxicity	Metho Asses icity	od: OECD ssment: Th	.000 mg/kg Test Guideline 423 he substance or mixture has no acute oral tox d on data from similar materials		
Acute	e dermal toxicity			> 2.000 mg/kg d on data from similar materials		
Not cl	corrosion/irritation lassified based on ava ponents:	ailable inform	ation.			
Speci	idopa:	: Rabb	it			
Resul			in irritatior)		
Magn	esium stearate:					
Speci		: Rabb				
Resul Rema			tin irritatior d on data f	rom similar materials		
Serio	us eye damage/eye	irritation				
	lassified based on ava		ation.			
<u>Com</u>	oonents:					
Carbi	idopa:					
Speci		: Rabb				
Resu	It	: Mild e	eye irritatio	n		
Starc						
Speci Resul		: Rabb : No ey	it ve irritation			
Magn	esium stearate:					
Speci		: Rabb				
Resul Rema		: No ey	e irritation	rom similar materials		
Rema	1172	. Base	a on uata t	IOIII SIIIIIIAI IIIALEIIAIS		



ersion .6	Revision Date: 10.10.2020		0S Number: 049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
Resp	iratory or skin sens	itizatio	n	
•••••	sensitization lassified based on av	ailable	information.	
•	iratory sensitizatior lassified based on av		information.	
Com	ponents:			
Levo	dopa:			
Speci Resul		:	Guinea pig Not a skin sensit	izer.
	idopa:			
Rema	arks	:	No data available	e
Starc	h:			
Test		:	Maximization Te	st
	es of exposure	:	Skin contact	
Speci Resul		:	Guinea pig negative	
Magn	esium stearate:			
Test		:	Maximization Te	st
	es of exposure	:	Skin contact	
Speci	ies	:	Guinea pig	
Metho		:	OECD Test Guid	deline 406
Resu		:	negative	
Rema	arks	:	Based on data fr	om similar materials
	cell mutagenicity			
	lassified based on av	ailable	information.	
	<u>ponents:</u>			
	dopa:	-	Toot Tumor De sta	
Geno	toxicity in vitro	:	Result: negative	erial reverse mutation assay (AMES)
			Test system: mo	mosomal aberration use lymphoma cells
			Result: equivoca	u .
			Test Type: Micro Test system: Ch Result: positive	onucleus test inese hamster lung cells
				chromatid exchange assay inese hamster lung cells

Carbidopa:



Version 5.6	Revision Date: 10.10.2020		Number: 19-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015		
Geno	toxicity in vitro		Test Type: Ba Result: positiv	cterial reverse mutation assay (AMES) e		
			Test Type: In Result: positiv	vitro mammalian cell gene mutation test e		
Geno	Genotoxicity in vivo :		Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative			
Cellu	lose:					
	toxicity in vitro		Fest Type: Ba Result: negati [,]	cterial reverse mutation assay (AMES) ve		
			Fest Type: In Result: negati	vitro mammalian cell gene mutation test ve		
Geno	toxicity in vivo		cytogenetic as Species: Mous	se function		
Starc	h:					
Geno	toxicity in vitro		Fest Type: Ba Result: negati [,]	cterial reverse mutation assay (AMES) ve		
Magn	esium stearate:					
Geno	toxicity in vitro	I	Result: negati	vitro mammalian cell gene mutation test ve ed on data from similar materials		
		I		romosome aberration test in vitro D Test Guideline 473 ve		
				ed on data from similar materials		
		I	Result: negati	cterial reverse mutation assay (AMES) ve ed on data from similar materials		
	n ogenicity lassified based on ava	ailable in	formation			
	ponents:					
	dopa:					
Speci Applio	ies cation Route sure time	: (Rat Dral 2 Years negative			



ersion S	Revision Date: 10.10.2020		0S Number: 049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
Carbi	dopa:			
	-		Det	
Speci		-	Rat Oral	
	cation Route sure time	:	96 weeks	
Expo		:	135 mg/kg body v	veight
Resu	t	:	negative	woight
Cellu	lose:			
Speci	es	:	Rat	
•	cation Route	:	Ingestion	
	sure time	:	72 weeks	
Resu		:	negative	
-	oductive toxicity ected of damaging the	unbo	rn child.	
Com	oonents:			
Levo	dopa:			
	s on fertility		Test Type: Fertilit	
LIICO	S OIT IEITIIITY	•	Species: Rat	^r y
			Application Route	o. Oral
				100 mg/kg body weight
				sting did not show any effects on fertility.
Effect	s on fetal development	t :	Test Type: Devel	opment
			Species: Rabbit	
			Application Route	
				oxicity: LOAEL: 125 mg/kg body weight
				etal malformations., Visceral malformations.
			Result: positive	
			Test Type: Devel	opment
			Species: Rat	
			Application Route	
			Developmental T	oxicity: LOAEL: 10 mg/kg body weight
			Test Type: Devel	opment
			Species: Mouse	
			Application Route	
				oxicity: LOAEL: 500 mg/kg body weight
				ts on fetal development.
			Result: positive	
Repro	oductive toxicity - As-	:	Some evidence c	f adverse effects on development, based o
sessn	-		animal experimer	
Carbi	dopa:			
	s on fertility		Test Type: Fertilit	tv
		•	Species: Rat	· ·
			Application Route	e: Oral



ersion S	Revision Date: 10.10.2020		9S Number: 049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
			Symptoms: Re	EL: 120 mg/kg body weight educed body weight I testing did not show any effects on fertility.
Effects on fetal development		:		se
				pit
Cellul	lose:			
Effects	s on fertility	:	Species: Rat	e-generation reproduction toxicity study oute: Ingestion ve
Effects on fetal development		:	Species: Rat	rtility/early embryonic development oute: Ingestion ve
Magn	esium stearate:			
Effects	s on fertility	:	reproduction/c Species: Rat Application Ro Method: OEC Result: negati	mbined repeated dose toxicity study with th levelopmental toxicity screening test oute: Ingestion D Test Guideline 422 ve ed on data from similar materials
Effects	s on fetal development	:	Species: Rat	nbryo-fetal development oute: Ingestion ve

STOT-repeated exposure

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

Components:

Levodopa:

Routes of exposure : Oral



Version 5.6	Revision Date: 10.10.2020	SDS Number: 51049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
	et Organs ssment	: Central nervo : Causes dam exposure.	ous system age to organs through prolonged or repeated
Repe	ated dose toxicity		
Com	ponents:		
Levo	dopa:		
Expo	EL cation Route sure time et Organs	: Rat : 100 mg/kg : Oral : 106 Weeks : Central nervo : Salivation	bus system
Expo		: Monkey : 100 mg/kg : Oral : 22 Weeks : Central nervo	ous system
Carbi	idopa:		
	EL cation Route sure time	: Rat : 25 mg/kg : Oral : 96 Weeks : No significan	t adverse effects were reported
	EL cation Route sure time	: Monkey : 135 mg/kg : Oral : 1 y : No significan	t adverse effects were reported
	EL EL cation Route sure time	: Dog : 5 mg/kg : 15 mg/kg : Oral : 238 d : Diarrhea, Vo	miting, Tremors
Cellu	lose:		
Speci NOAI Applio	ies	: Rat : >= 9.000 mg. : Ingestion : 90 Days	/kg
Starc	h:		
Speci NOAI Applic		: Rat : >= 2.000 mg. : Skin contact	/kg



	Revision Date: 10.10.2020		DS Number: 049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015			
Exposure time Method		: 28 Days : OECD Test Guideline 410					
Magn	esium stearate:						
Species NOAEL Application Route Exposure time Remarks		 Rat > 100 mg/kg Ingestion 90 Days Based on data from similar materials 					
-	ation toxicity assified based on availa	ble	information.				
Ехре	rience with human exp	osı	ıre				
<u>Comp</u>	oonents:						
Levo	lopa:						
Ingest	lion	:	Symptoms: Nau ness	isea, central nervous system effects, Drowsi-			
Carbi	dopa:						
1	ion		• • •	1			
	12. ECOLOGICAL INFO	: DRI		oluntary movement			
CTION Ecoto <u>Comp</u>	12. ECOLOGICAL INFO	: DRI		oluntary movement			
CTION Ecoto <u>Comp</u> Levoo	12. ECOLOGICAL INFO exicity <u>conents:</u> dopa:		MATION				
CTION Ecoto <u>Comp</u> Levoo	12. ECOLOGICAL INFO		MATION	magna (Water flea)): 16 mg/l			
CTION Ecoto <u>Comp</u> Levoo	12. ECOLOGICAL INFO exicity conents: dopa: ty to daphnia and other ic invertebrates		MATION EC50 (Daphnia	magna (Water flea)): 16 mg/l			
CTION Ecoto Comp Levoo Toxici aquati Carbi Toxici	12. ECOLOGICAL INFO points: dopa: ty to daphnia and other ic invertebrates dopa: ty to daphnia and other	:	EC50 (Daphnia Exposure time: EC50 (Daphnia	magna (Water flea)): 16 mg/l 48 h magna (Water flea)): 35,3 mg/l			
CTION Ecoto Comp Levoo Toxici aquati Carbi Toxici	12. ECOLOGICAL INFO exicity conents: dopa: ty to daphnia and other ic invertebrates dopa:	:	EC50 (Daphnia Exposure time: EC50 (Daphnia Exposure time:	magna (Water flea)): 16 mg/l 48 h magna (Water flea)): 35,3 mg/l			
CTION Ecoto Comp Levoo Toxici aquati Carbi Toxici	12. ECOLOGICAL INFO	:	EC50 (Daphnia Exposure time: EC50 (Daphnia Exposure time:	magna (Water flea)): 16 mg/l 48 h magna (Water flea)): 35,3 mg/l 48 h			
CTION Ecoto Comp Levoo Toxici aquati Carbi Toxici aquati	12. ECOLOGICAL INFO	:	MATION EC50 (Daphnia Exposure time: EC50 (Daphnia Exposure time: Method: OECD LC50 (Oryzias I Exposure time:	magna (Water flea)): 16 mg/l 48 h magna (Water flea)): 35,3 mg/l 48 h Test Guideline 202 atipes (Japanese medaka)): > 100 mg/l			
CTION Ecoto Comp Levoo Toxici aquati Carbi Toxici aquati	12. ECOLOGICAL INFO	:	MATION EC50 (Daphnia Exposure time: EC50 (Daphnia Exposure time: Method: OECD LC50 (Oryzias I Exposure time:	magna (Water flea)): 16 mg/l 48 h magna (Water flea)): 35,3 mg/l 48 h Test Guideline 202 atipes (Japanese medaka)): > 100 mg/l 48 h			
CTION Ecoto Comp Levoo Toxici aquati Carbi Toxici aquati Carbi Toxici Aquati	12. ECOLOGICAL INFO	:	MATION EC50 (Daphnia Exposure time: EC50 (Daphnia Exposure time: Method: OECD LC50 (Oryzias I Exposure time: Remarks: Base LC50 (Leuciscu Exposure time: Method: DIN 38	magna (Water flea)): 16 mg/l 48 h magna (Water flea)): 35,3 mg/l 48 h Test Guideline 202 atipes (Japanese medaka)): > 100 mg/l 48 h d on data from similar materials s idus (Golden orfe)): > 100 mg/l 48 h			



rsion S	Revision Date: 10.10.2020	-	OS Number: 049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
			Method: Directi Remarks: Base	: Water Accommodated Fraction ve 67/548/EEC, Annex V, C.2. ed on data from similar materials e limit of solubility.
Toxicit plants	ty to algae/aquatic	:	mg/l Exposure time: Test substance Method: OECD Remarks: Base	irchneriella subcapitata (green algae)): > 1 72 h : Water Accommodated Fraction Test Guideline 201 ed on data from similar materials he limit of solubility.
			mg/l Exposure time: Test substance Method: OECD	lokirchneriella subcapitata (green algae)): > 1 72 h : Water Accommodated Fraction Test Guideline 201 ed on data from similar materials
Toxicit	ty to microorganisms	:	Exposure time: Test substance	monas putida): > 100 mg/l 16 h : Water Accommodated Fraction ed on data from similar materials
Persis	stence and degradab	ility		
<u>Comp</u>	onents:			
Cellul Biodeg	ose: gradability	:	Result: Readily	biodegradable.
-	esium stearate: gradability	:	Result: Not bio Remarks: Base	degradable. Id on data from similar materials
Bioac	cumulative potential			
<u>Comp</u>	onents:			
	lopa: on coefficient: n- ol/water	:	log Pow: -2,39	
_	esium stearate: on coefficient: n-	:	log Pow: > 4	
	ol/water			
	ol/water i ty in soil ta available			



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
5.6	10.10.2020	51049-00016	Date of first issue: 23.01.2015

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture					
Argentina. Carcinogenic Sub Registry.	stances and Agents : Not applicable				
Control of precursors and essential chemicals for the : Calcium oxide preparation of drugs.					
International Regulations					
The ingredients of this product are reported in the following inventories:					
AICS	: not determined				
DSL	: not determined				
IECSC	: not determined				

SECTION 16. OTHER INFORMATION

Further information

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

Full text of other abbreviations



Version 5.6	Revision Date: 10.10.2020	SDS Number: 51049-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015	
ACGIH AR OE	-		Threshold Limit Values (TLV) cupational Exposure Limits	
ACGIH / TWA AR OEL / CMP		8-hour, time-weighted averageTLV (Threshold Limit Value)		

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

AR / Z8