Version



Date of last issue: 23.03.2020

Carbidopa / Levodopa Formulation

SDS Number:

Revision Date:

version 6.6	10.10.2020	50121-00016	Date of first issue: 23.03.2020 Date of first issue: 23.01.2015
SECTION	1. PRODUCT AND CO	MPANY IDENTIFIC	ATION
	uct name		evodopa Formulation
	afacturer or supplier's (•	
	pany name of supplier	: Organon & Co : Avenida 16 d). e Septiembre No. 301 chimilco Mexico 16090
	bhone gency telephone il address	: 52 55 572844 : 215-631-6999 : EHSSTEWAR	
Reco	mmended use of the c	hemical and restri	ctions on use
Reco	mmended use	: Pharmaceutic	al
SECTION	2. HAZARDS IDENTIFI	CATION	
GHS	Classification		
Acute	e toxicity (Oral)	: Category 4	
Repro	oductive toxicity	: Category 2	
	ific target organ toxicity eated exposure (Oral)	: Category 1 (C	entral nervous system)
GHS	label elements		
	rd pictograms		!
Signa	al Word	: Danger	
Haza	rd Statements	H372 Causes	if swallowed. cted of damaging the unborn child. damage to organs (Central nervous system) nged or repeated exposure if swallowed.
Preca	autionary Statements	P202 Do not h and understoo P260 Do not h P264 Wash sh P270 Do not e P280 Wear pr face protection Response: P301 + P312 CENTER or d	reathe dust. in thoroughly after handling. eat, drink or smoke when using this product. otective gloves/ protective clothing/ eye protection/



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020	
6.6	10.10.2020	50121-00016	Date of first issue: 23.01.2015	

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

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

: Mixture

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

Components

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

SECTION 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	Harmful if swallowed. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure if swallowed. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection,



Version 6.6	Revision Date: 10.10.2020		OS Number: 121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015	
No	tes to physician	:	when the potentia	nmended personal protective equipment I for exposure exists (see section 8). cally and supportively.	
SECTIO	ON 5. FIRE-FIGHTING MEA	ASL	JRES		
Su	Suitable extinguishing media		: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical		
	suitable extinguishing dia	:	None known.		
	Specific hazards during fire fighting		concentrations, and potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. bustion products may be a hazard to health.	
	Hazardous combustion prod- ucts		Carbon oxides Metal oxides		
Sp od:	ecific extinguishing meth- S	:	 Use extinguishing measures that are appropriate to loc cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is sa so. Evacuate area. 		
	ecial protective equipment fire-fighters	:		e, wear self-contained breathing apparatus. ective 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.
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.

SAFETY DATA SHEET



Carbidopa / Levodopa Formulation

Version 6.6	Revision Date: 10.10.2020	SDS Number: 50121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
SECTION	7. HANDLING AND ST	ORAGE	
Tech	nical measures	causing an exp Provide adequ	y may accumulate and ignite suspended dust plosion. ate precautions, such as electrical grounding or inert atmospheres.
	I/Total ventilation be on safe handling	 Use only with a Do not breather Do not swallow Avoid contact Avoid prolonge Wash skin thou Handle in accor practice, based assessment Minimize dust Keep containe Keep away fro Take precaution Do not eat, drive 	adequate ventilation. dust. /.
Hygie	ene measures	flushing system place. When using do Wash contamin The effective o engineering co appropriate de industrial hygie	chemical is likely during typical use, provide eye ns and safety showers close to the working o not eat, drink or smoke. hated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the trative controls.
Conc	litions for safe storage	: Keep in proper Store locked u	ly labeled containers.
Mate	rials to avoid		ith the following product types: g agents

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
Levodopa	59-92-7	TWA	500 µg/m3 (OEB 2)	Internal
Carbidopa	38821-49-7	TWA	2,000 µg/m3 (OEB 1)	Internal
Cellulose	9004-34-6	VLE-PPT	10 mg/m ³	NOM-010- STPS-2014



rsion S			S Number: 121-00016		t issue: 23.03.2020 st issue: 23.01.2015		
1		1			40		
Starch			9005-25-8	TWA VLE-PPT	10 mg/m ³ 10 mg/m ³	ACGIH NOM-010-	
					40	STPS-201	
Magne	esium stearate		557-04-0	TWA VLE-PPT	10 mg/m ³ 10 mg/m ³	ACGIH NOM-010- STPS-201	
				TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH	
				TWA (Respirable particulate matter)	3 mg/m ³	ACGIH	
Engine	eering measures	:	compound. All engineeri design and c	ng controls shou	trols to minimize exp Id be implemented by dance with GMP prin d the environment.	/ facility	
Persor	nal protective equipme	ent					
·	atory protection er type	:	exposure as	sessment demor ed guidelines, us	tilation is not availab Istrates exposures ou e respiratory protection	utside the	
Hand p	protection terial	:		sistant gloves			
Eye pr	otection	:	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				
Skin a	nd body protection	:	aerosols. Work uniforn	n or laboratory co	pat.		
	9. PHYSICAL AND CHE	MIC	CAL PROPE	RTIES			
Appea	rance	:	powder				
Color		:	No data ava	ilable			
Odor		:	odorless				
Odor T	Threshold	:	No data available				
рН		:	No data ava	ilable			
Meltinç	g point/freezing point	:	No data ava	ilable			
Initial b range	poiling point and boiling	:	No data ava	ilable			

SAFETY DATA SHEET



Carbidopa / Levodopa Formulation

Version 6.6	Revision Date: 10.10.2020		S Number: 21-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
Evap	oration rate	:	No data available	9
Flam	mability (solid, gas)	:	May form explosing the second	ive dust-air mixture during processing, means.
Flam	mability (liquids)	:	No data available	9
	er explosion limit / Upper nability limit	:	No data available	9
	er explosion limit / Lower nability limit	:	No data available	9
Vapo	or pressure	:	No data available	9
Relat	tive vapor density	:	No data available	9
Relat	tive density	:	No data available	9
Dens	sity	:	No data available)
	oility(ies) /ater solubility	:	No data available	9
	tion coefficient: n- nol/water	:	No data available	9
	ignition temperature	:	No data available	9
Deco	mposition temperature	:	No data available	9
Visco Vi	osity iscosity, dynamic	:	No data available	
Vi	iscosity, kinematic	:	No data available)
Explo	osive properties	:	Not explosive	
Oxidi	izing properties	:	The substance o	r mixture is not classified as oxidizing.
Mole	cular weight	:	No data available	9
Partie	cle size	:	No data available	9

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. 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.

SAFETY DATA SHEET



/ersion 6.6	Revision Date: 10.10.2020		S Number: 121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015				
	npatible materials rdous decomposition lcts	:	Avoid dust formation.Oxidizing agentsNo hazardous decomposition products are known.					
SECTION	11. TOXICOLOGICA	LINF	ORMATION					
Inhala Skin o Inges	contact	es of	exposure					
Harm	e toxicity ful if swallowed.							
Produ Acute	e oral toxicity	:	Acute toxicity es Method: Calcula	stimate: 1,952 mg/kg ation method				
Com	oonents:							
Levo	dopa:							
Acute	oral toxicity	:	LD50 (Rat): 1,7	80 mg/kg				
			LD50 (Mouse):	2,363 mg/kg				
Carbi	idopa:							
Acute	oral toxicity	:	LD50 (Rat): 4,8	10 mg/kg				
			LD50 (Mouse):	1,750 mg/kg				
Cellu Acute	lose:	:	LD50 (Rat): > 5	,000 mg/kg				
Acute	inhalation toxicity	:	LC50 (Rat): > 5 Exposure time: Test atmospher	4 h				
Acute	e dermal toxicity	:	LD50 (Rabbit):	> 2,000 mg/kg				
Starc	h:							
	e oral toxicity	:	LD50 (Rat): > 5	,000 mg/kg				
Acute	e dermal toxicity	:	LD50 (Rabbit):	> 2,000 mg/kg				
Magn	esium stearate:							
-	e oral toxicity	:		,000 mg/kg Test Guideline 423 ne substance or mixture has no acute oral to				



rsion	Revision Date: 10.10.2020		S Number: 121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
			Remarks: Bas	ed on data from similar materials
Acute	dermal toxicity	:		: > 2,000 mg/kg sed on data from similar materials
	corrosion/irritation			
Not cl	assified based on ava	ailable	information.	
<u>Comp</u>	<u>ponents:</u>			
Carbi	dopa:			
Speci		:	Rabbit	
Resul	t	:	No skin irritati	on
Magn	esium stearate:			
Speci		:	Rabbit	
Resul		:	No skin irritati	
Rema	irks	:	Based on data	a from similar materials
Serio	us eye damage/eye	irritati	on	
	assified based on ava			
<u>Com</u>	<u>oonents:</u>			
Carbi	dopa:			
Speci	-	:	Rabbit	
Resul	t	:	Mild eye irritat	tion
Starc	h:			
Speci		:	Rabbit	
Resul		:	No eye irritatio	on
Magn	esium stearate:			
Speci		:	Rabbit	
Resul	t	:	No eye irritatio	
Rema	urks	:	Based on data	a from similar materials
Resp	iratory or skin sensi	tizatio	n	
Skin	sensitization			
	assified based on ava	ailable	information.	
Resp	iratory sensitization			
Not cl	assified based on ava	ailable	information.	
Com	<u>oonents:</u>			
Levo	dopa:			
Speci	es	:	Guinea pig	



rsion	Revision Date: 10.10.2020	SDS Number: 50121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
Carbi	dopa:		
Rema	rks	: No data ava	ailable
Starc	h:		
Test T	уре	: Maximizatio	n Test
Routes of exposure Species		: Skin contac	t
		: Guinea pig	
Resul	t	: negative	
Magn	esium stearate:		
Test T	уре	: Maximizatio	n Test
	s of exposure	: Skin contac	t
Speci		: Guinea pig	
Metho			Guideline 406
Resul		: negative	ata from aimilar matariala
Rema	IKS	: based on d	ata from similar materials
	cell mutagenicity		
	assified based on av	ailable information.	
-	oonents:		
Levoo	dopa:		
Genot	oxicity in vitro	: Test Type: l Result: neg	Bacterial reverse mutation assay (AMES) ative
			Chromosomal aberration n: mouse lymphoma cells ivocal
			Micronucleus test n: Chinese hamster lung cells tive
			sister chromatid exchange assay n: Chinese hamster lung cells tive
Carbi	dopa:		
	oxicity in vitro	: Test Type: I Result: posi	Bacterial reverse mutation assay (AMES) tive
		Test Type: Result: posi	In vitro mammalian cell gene mutation test tive
	oxicity in vivo	: Test Type: Species: Mo	Micronucleus test



Vers 6.6	sion	Revision Date: 10.10.2020		0S Number: 121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015		
	Genoto	oxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)		
				Test Type: In vitro Result: negative	o mammalian cell gene mutation test		
	Genotoxicity in vivo			Test Type: Mammalian erythrocyte micronucleus test (in cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative			
	Starch	:					
	Genoto	oxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)		
	Magne	sium stearate:					
	-	oxicity in vitro	:	Result: negative	o mammalian cell gene mutation test on data from similar materials		
				Method: OECD T Result: negative	nosome aberration test in vitro est Guideline 473 on data from similar materials		
				Result: negative	rial reverse mutation assay (AMES) on data from similar materials		
		ogenicity ssified based on availa	able	information.			
	Compo	onents:					
	Levod	ona.					
	Specie	•	:	Rat			
	Applica	ation Route	:	Oral			
	Exposi Result	ure time	:	2 Years negative			
	Carbid	lona.					
	Specie	-	:	Rat			
	Applica	ation Route	:	Oral			
	Exposi	ure time	-	96 weeks 135 mg/kg body v	veight		
	Result		:	negative	voigne		
	Cellulo	ose:					
	Specie		:	Rat			
		ation Route ure time	:	Ingestion 72 weeks			
			•				



ersion .6	Revision Date: 10.10.2020	-	OS Number: 121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
Resu	lt	:	negative	
-	oductive toxicity ected of damaging the u	nbo	rn child.	
<u>Com</u>	ponents:			
Levo	dopa:			
Effec	ts on fertility	:		-
Effec	ts on fetal development	:		
			Test Type: Develor Species: Rat Application Route Developmental To	
Repr sessi	oductive toxicity - As- ment	:	Some evidence o animal experimer	f adverse effects on development, based o ts.
Carb	idopa:			
Effec	ts on fertility	:	Symptoms: Redu	: Oral 120 mg/kg body weight
Effec	ts on fetal development	:	Test Type: Develor Species: Mouse Application Route Developmental To Result: No teratos	: Oral oxicity: NOAEL: 120 mg/kg body weight
			Test Type: Develor Species: Rabbit Application Route Developmental To	



Versio 6.6	on	Revision Date: 10.10.2020		S Number: 121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
				Result: No teratog	genic effects.
С	ellulo	se:			
E	ffects	on fertility	:	Test Type: One-g Species: Rat Application Route Result: negative	eneration reproduction toxicity study : Ingestion
E	ffects of	on fetal development	:	Test Type: Fertility Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion
Ν	lagnes	sium stearate:			
E	ffects	on fertility	:	reproduction/deve Species: Rat Application Route Method: OECD Te Result: negative	
E	ffects	on fetal development	:	Species: Rat Application Route Result: negative	o-fetal development : Ingestion on data from similar materials

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

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

Components:

Levodopa:

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

Repeated dose toxicity

Components:

Levodopa:

Species	:	Rat
LOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	106 Weeks
Target Organs	:	Central nervous system



Symptoms::SalivationSpecies::100 mg/kgApplication Route::OralExposure time::22 WeeksTarget Organs::Central nervous systemCarbidopa:Species::RatLOAEL::25 mg/kgApplication Route::OralExposure time::96 WeeksRemarks::No significant adverse effects were reportedSpecies::MonkeyNOAEL::135 mg/kgApplication Route::YoAEL::135 mg/kgApplication Route::Species::NOAEL::Species::DogNOAEL::Species::DogNOAEL::Species <td:< td="">DogNOAEL::Application Route::Species<td::< td="">DogNOAEL::Species<td::< td="">DogNOAEL::Species<td::< td="">Diarrhea, Vomiting, TremorsElulose:Species<td::< td="">Species<td::< td="">Species<td:< <="" th=""><th>Version 6.6</th><th>Revision Date: 10.10.2020</th><th>SDS Number: 50121-00016</th><th>Date of last issue: 23.03.2020 Date of first issue: 23.01.2015</th></td:<></td:<></td:<></td:<></td:<></td:<></td:<></td:<></td:<></td:<></td:<></td:<></td::<></td::<></td::<></td::<></td::<></td:<>	Version 6.6	Revision Date: 10.10.2020	SDS Number: 50121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
LOAEL : 100 mg/kg Application Route : Oral Exposure time : 22 Weeks Target Organs : Central nervous system Carbidopa: Species : Rat LOAEL : 25 mg/kg Application Route : Oral Exposure time : 96 Weeks Remarks : No significant adverse effects were reported Species : Monkey NOAEL : 135 mg/kg Application Route : Oral Exposure time : 1 y Remarks : No significant adverse effects were reported Species : Monkey NOAEL : 135 mg/kg Application Route : Oral Exposure time : 1 y Remarks : No significant adverse effects were reported Species : Dog NOAEL : 15 mg/kg Application Route : Oral Exposure time : 238 d Symptoms : Diarrhea, Vomiting, Tremors Cellulose: Species : Rat NOAEL : Ingestion Exposure time : 90 Days Starch: Species : Rat NOAEL : Second Exposure time : 28 Days Method : OECD Test Guideline 410 Magnesium stearate: Species : Rat NOAEL : 2 > 100 mg/kg Application Route : 28 Days Method : > 100 mg/kg Application Route : 28 Days Method : > 100 mg/kg Application Route : 90 Days	Symp	toms	: Salivation	
Species:RatLOAEL::25 mg/kgApplication Route::OralExposure time::96 WeeksRemarks::No significant adverse effects were reportedSpecies::MonkeyNOAEL::135 mg/kgApplication Route:OralExposure time:1 yRemarks:No significant adverse effects were reportedSpecies:DogNOAEL::Species:DogNOAEL::Synotoms:Diarrhea, Vomiting, TremorsCellulose:::Species:RatNOAEL::Species:RatNOAEL::Species:RatNOAEL::Species:RatNOAEL::Species:RatNOAEL::Species:RatNOAEL::>Species:RatNOAEL::>Species:RatNOAEL::>Species:RatNOAEL::>Species:RatNOAEL::>Species:RatNOAEL::>Species:RatNOAEL <td:< td="">:<</td:<>	LOAE Applic Expos	L cation Route sure time	: 100 mg/kg : Oral : 22 Weeks	us system
LOAEL :: 25 mg/kg Application Route :: 0ral 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 :: 238 d Symptoms :: Diarrhea, Vomiting, Tremors Cellulose: : Species : Rat NOAEL :> 9,000 mg/kg Application Route : Ingestion Exposure time :: 90 Days Starch: : Species : Rat NOAEL :: > 28 Days Method : OECD Test Guideline 410 Magnesium	Carbi	dopa:		
NOAEL:135 mg/kgApplication Route:OralExposure time:1 yRemarks:No significant adverse effects were reportedSpecies::DogNOAEL:Species::DogNOAEL:LOAEL::Species::Application Route::Oral:Exposure time::238 d:Symptoms::Diarrhea, Vomiting, TremorsCellulose:Species:RatNOAEL:NOAEL::>= 9,000 mg/kgApplication Route::Ingestion:Exposure time::90 Days:Starch::Species::Species::Species:RatNOAEL:>= 2,000 mg/kgApplication Route:Species:RatNOAELMethod:OECD Test Guideline 410Magnesium stearate:Species:Species:RatNOAEL:>= 20 Days	LOAE Applic Expos	L cation Route sure time	: 25 mg/kg : Oral : 96 Weeks	adverse effects were reported
NOAEL:5 mg/kgLOAEL:15 mg/kgApplication Route:OralExposure time:238 dSymptoms:Diarrhea, Vomiting, TremorsCellulose:Species:RatNOAEL:>= 9,000 mg/kgApplication Route:IngestionExposure time:90 DaysStarch::Species:RatNOAEL:>= 2,000 mg/kgApplication Route:Skin contactExposure time:>= 2,000 mg/kgApplication Route:Skin contactExposure time:28 DaysMethod:OECD Test Guideline 410Magnesium stearate::Species:RatNOAEL:> 100 mg/kgApplication Route:90 Days	NOAE Applic Expos	EL cation Route sure time	: 135 mg/kg : Oral : 1 y	adverse effects were reported
Species : Rat NOAEL : >= 9,000 mg/kg Application Route : Ingestion Exposure time : 90 Days Starch: Species : Rat NOAEL : 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 Application Route : NOAEL Magnesium stearate: : > 100 mg/kg Application Route : > 100 mg/kg Application Route : > 100 mg/kg Application Route : Ingestion Exposure time : 90 Days	NOAE LOAE Applic Expos	EL EL cation Route sure time	: 5 mg/kg : 15 mg/kg : Oral : 238 d	niting, Tremors
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 Application Route : Ingestion Exposure time : 90 Days	Speci NOAE Applic	es EL cation Route	: >= 9,000 mg/k : Ingestion	g
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 Application Route : Ingestion Exposure time : 90 Days	Starc	h:		
Species:RatNOAEL:> 100 mg/kgApplication Route:IngestionExposure time:90 Days	NOAE Applic Expos	EL cation Route sure time	: >= 2,000 mg/k : Skin contact : 28 Days	-
NOAEL:> 100 mg/kgApplication Route:IngestionExposure time:90 Days	Magn	esium stearate:		
Remarks : Based on data from similar materials	NOAE Applic Expos	EL cation Route sure time	: > 100 mg/kg : Ingestion : 90 Days	a from similar materials

Aspiration toxicity

Not classified based on available information.



berience with human expension mponents: rodopa: estion bidopa: estion N 12. ECOLOGICAL INFO ptoxicity mponents: rodopa: icity to daphnia and other atic invertebrates	:	Symptoms: Nausea, central nervous system effects, Drowsi- ness Symptoms: involuntary movement
rodopa: estion bidopa: estion N 12. ECOLOGICAL INFO ptoxicity mponents: rodopa: icity to daphnia and other	: DRM	ness Symptoms: involuntary movement
estion bidopa: estion N 12. ECOLOGICAL INFO ptoxicity mponents: rodopa: icity to daphnia and other	: DRM	ness Symptoms: involuntary movement
bidopa: estion N 12. ECOLOGICAL INFO otoxicity mponents: rodopa: icity to daphnia and other	: : DRM	ness Symptoms: involuntary movement
N 12. ECOLOGICAL INFO otoxicity mponents: rodopa: icity to daphnia and other	: DRM	
N 12. ECOLOGICAL INFO ptoxicity mponents: rodopa: icity to daphnia and other	: DRM	
otoxicity mponents: rodopa: icity to daphnia and other	DRN	ΛΑΤΙΟΝ
mponents: rodopa: icity to daphnia and other		
rodopa: icity to daphnia and other		
icity to daphnia and other		
	:	EC50 (Daphnia magna (Water flea)): 16 mg/l Exposure time: 48 h
bidopa:		
icity to daphnia and other atic invertebrates	:	EC50 (Daphnia magna (Water flea)): 35.3 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
lulose:		
icity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
gnesium stearate:		
icity to fish	:	LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials
icity to daphnia and other atic 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.
icity to algae/aquatic nts	:	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.
i	atic invertebrates city to algae/aquatic	city to algae/aquatic :



ersion .6	Revision Date: 10.10.2020		DS Number: 121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
			Method: OECD	72 h : Water Accommodated Fraction Test Guideline 201 d on data from similar materials
Toxici	ity to microorganisms	:	Exposure time: Test substance	nonas putida): > 100 mg/l 16 h : Water Accommodated Fraction d on data from similar materials
Persi	stence and degradab	ility		
Comp	oonents:			
Cellu	lose:			
Biode	gradability	:	Result: Readily	biodegradable.
-	esium stearate: gradability	:	Result: Not bioo Remarks: Base	degradable. d on data from similar materials
Bioad	cumulative potential			
<u>Comp</u>	oonents:			
	dopa: on coefficient: n- ol/water	:	log Pow: -2.39	
Partiti	esium stearate: on coefficient: n- ol/water	:	log Pow: > 4	
	l ity in soil Ita available			
Other	adverse effects ata available			

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods	
Waste from residues Contaminated packaging	 Dispose of in accordance with local regulations. 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



Version 6.6	Revision Date: 10.10.2020	SDS Number: 50121-00016	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015
	-DGR egulated as a dangerd	ous good	
	G-Code egulated as a dangero	ous good	
	sport in bulk accordi	-	RPOL 73/78 and the IBC Code
Dom	estic regulation		
	-002-SCT egulated as a dangerc	ous good	
-	ial precautions for u	ser	
SECTION	15. REGULATORY I	NFORMATION	
Safet mixtu		nmental regulations/	legislation specific for the substance or
	ral Law for the control ntial chemical products		rs, : Not applicable

The ingredients of this product are reported in the following inventories:	The ingredients of this	product are repor	rted in the followir	q inventories:
--	-------------------------	-------------------	----------------------	----------------

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH NOM-010-STPS-2014	USA. ACGIH Threshold Limit Values (TLV) Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Con- trol - Appendix 1 Occupational Exposure Limits
ACGIH / TWA NOM-010-STPS-2014 / VLE- PPT	8-hour, time-weighted average Time weighted average 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



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.6	10.10.2020	50121-00016	Date of first issue: 23.01.2015

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

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 : 10.10.2020

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

MX / Z8