

according to GB/T 16483 and GB/T 17519

## Alendronate / Vitamin D Formulation

Versior 5.10	n Revision Date: 2020/03/23		S Number: 043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
1. PRO	DUCT AND COMPANY ID	ENT	IFICATION	
Pr	oduct name	:	Alendronate / Vit	amin D Formulation
Ma	anufacturer or supplier's o	detai	ils	
Co	ompany	:	Organon & Co.	
Ac	ldress	:	30 Hudson Stree Jersey City, New	et, 33nd floor v Jersey, U.S.A 07302
Те	lephone	:	551-430-6000	
Er	nergency telephone numbe	r :	215-631-6999	
E-	mail address	:	EHSSTEWARD	@organon.com
Re	ecommended use of the cl	hem	ical and restriction	ons on use

#### 2. HAZARDS IDENTIFICATION

#### **Emergency Overview**

• •		
Appearance Colour Odour	:	powder off-white odourless
	damaging t	irritation. Causes serious eye damage. May cause respiratory he unborn child. May cause damage to organs through pro- nful to aquatic life.

### **GHS Classification**

Acute toxicity (Oral)	:	Category 4
Skin corrosion/irritation	:	Category 2
Serious eye damage/eye irri- tation	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - single exposure	:	Category 3
Specific target organ toxicity - repeated exposure	:	Category 2
Short-term (acute) aquatic hazard	:	Category 3

Recommended use : Pharmaceutical

#### **GHS** label elements



according to GB/T 16483 and GB/T 17519

Version 5.10	Revision Date: 2020/03/23	SDS Number: 22043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
Haza	rd pictograms		
Signa	al word	: Danger	• •
Haza	rd statements	H315 Causes H318 Causes H335 May ca H361d Suspe H373 May ca peated expos	l if swallowed. skin irritation. serious eye damage. use respiratory irritation. cted of damaging the unborn child. use damage to organs through prolonged or re- ure. I to aquatic life.
Preca	autionary statements	P202 Do not I and understoo P260 Do not I P264 Wash s P270 Do not o P271 Use onI P273 Avoid re	breathe dust. kin thoroughly after handling. eat, drink or smoke when using this product. y outdoors or in a well-ventilated area. elease to the environment. rotective gloves/ protective clothing/ eye protec-
		CENTER/ dod P302 + P352 P304 + P340 and keep com doctor if you f P305 + P351 water for seve and easy to d CENTER/ dod P308 + P313 attention. P332 + P313 tion. P362 + P364 reuse.	+ P338 + P310 IF IN EYES: Rinse cautiously with eral minutes. Remove contact lenses, if present o. Continue rinsing. Immediately call a POISON
		<b>Storage:</b> P405 Store lo	cked up.
		<b>Disposal:</b> P501 Dispose disposal plant	e of contents/ container to an approved waste

according to GB/T 16483 and GB/T 17519



## Alendronate / Vitamin D Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
5.10	2020/03/23	22043-00016	Date of first issue: 2014/10/15

#### Physical and chemical hazards

Not classified based on available information.

#### Health hazards

Harmful if swallowed. Causes skin irritation. Causes serious eye damage. Suspected of damaging the unborn child. May cause respiratory irritation. May cause damage to organs through prolonged or repeated exposure.

#### **Environmental hazards**

Harmful to aquatic life.

#### Other hazards which do not result in classification

May form explosive dust-air mixture during processing, handling or other means.

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

Substance / Mixture	:	Mixture
---------------------	---	---------

#### Components

CAS-No.	Concentration (% w/w)
9004-34-6	>= 30 -< 50
121268-17-5	>= 25 -< 30
67-97-0	>= 0.025 -< 0.1
	9004-34-6 121268-17-5

#### 4. FIRST AID MEASURES

General advice :	In the case of accident or if you feel unwell, seek medical ad- vice 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 plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact :	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.
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. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

according to GB/T 16483 and GB/T 17519



Version 5.10	Revision Date: 2020/03/23		0S Number: 043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
	ction of first-aiders s to physician	:	and use the recor when the potentia	ers should pay attention to self-protection, nmended personal protective equipment Il for exposure exists (see section 8). cally and supportively.
5. FIREFIC	GHTING MEASURES			
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
Unsu media	itable extinguishing	:	None known.	
	ific hazards during fire-	:	concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. pustion products may be a hazard to health.
Haza ucts	rdous combustion prod-	:	Carbon oxides Nitrogen oxides (I Phosphorus comp Metal oxides	
Speci ods	ific extinguishing meth-	:	cumstances and t Use water spray t Remove undama so.	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	ial protective equipment efighters	:		e, wear self-contained breathing apparatus. tective equipment.
6. ACCIDI	ENTAL RELEASE MEA	SUF	RES	
tive e	onal precautions, protec- quipment and emer- / procedures	:		tective equipment. ing advice and personal protective equip- ations.
Envir	onmental precautions	:	Prevent further le Retain and dispos	e environment must be avoided. akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages red.
	ods and materials for inment and cleaning up	:	tainer for disposa Avoid dispersal or with compressed Dust deposits sho es, as these may leased into the at Local or national posal of this mate	dust in the air (i.e., clearing dust surfaces

according to GB/T 16483 and GB/T 17519



## Alendronate / Vitamin D Formulation

Version 5.10	Revision Date: 2020/03/23	SDS Number: 22043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
		Sections 13 ar	gulations are applicable. nd 15 of this SDS provide information regarding r national requirements.
7. HANDI	LING AND STORAGE		
Hane	dling		
Tech	nical measures	causing an ex Provide adequ	ty may accumulate and ignite suspended dust plosion. late precautions, such as electrical grounding or inert atmospheres.
Loca	I/Total ventilation		ntilation is unavailable, use with local exhaust
	ce on safe handling	: Do not get on Do not breathe Do not swallow Do not get in e Handle in acco practice, base sessment Keep containe Already sensit regarding work Minimize dust Keep containe Keep away fro Take precautio Take care to p environment.	v. eyes. ordance with good industrial hygiene and safety d on the results of the workplace exposure as- er tightly closed. ised individuals should consult their physician king with respiratory irritants or sensitisers. generation and accumulation. er closed when not in use. im heat and sources of ignition. onary measures against static discharges. revent spills, waste and minimize release to the
	dance of contact	: Oxidizing ager	115
	age ditions for safe storage erials to avoid	Store locked u Keep tightly cl Keep in a cool Store in accord	
Pack	aging material	Strong oxidizir	ng agents terial: None known.
1 401			

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	PC-TWA	10 mg/m3	GBZ 2.1- 2007
		TWA	10 mg/m3	ACGIH
Alendronate	121268-17-5	TWA	20 µg/m3 (OEB 3)	Internal



according to GB/T 16483 and GB/T 17519

# Alendronate / Vitamin D Formulation

sion )	Revision Date: 2020/03/23	-	S Number: 043-00016		t issue: 2019/09/13 t issue: 2014/10/15	
		I		Min e lineit	200	
Calaa	alaifaral		<u> </u>	Wipe limit TWA	200 µg/100 cm <sup>2</sup>	Internal
Colec	alciferol		67-97-0		5 μg/m3 (OEB 4)	Internal
				Wipe limit	50 µg/100 cm <sup>2</sup>	Internal
Engir	neering measures	:	design and op protect produc Containment t are required to	erated in accord cts, workers, and echnologies sui o control at sour l to uncontrolled ces).	d be implemented by dance with GMP prind d the environment. table for controlling c ce and to prevent mig areas (e.g., open-fa	ciples to compounds gration of
Perso	onal protective equip	ment				
Respi	ratory protection	:	sure assessm	ent demonstrate	tilation is not availabl es exposures outside spiratory protection.	
Filt	ter type	:	Particulates ty			
Eye/fa	ace protection	:	If the work env mists or aeros Wear a facesh	vironment or act ols, wear the ap hield or other ful	shields or goggles. ivity involves dusty copropriate goggles. I face protection if the he face with dusts, m	ere is a
Skin a	and body protection	:	Additional boo task being per posable suits)	formed (e.g., sle to avoid expose te degowning te	at. uld be used based u eevelets, apron, gaur ed skin surfaces. echniques to remove	ntlets, dis-
Hand	protection		oontaminated	olotining.		
Ma	aterial	:	Chemical-resi	stant gloves		
	emarks ne measures	:	eye flushing s ing place. When using d Wash contam The effective of engineering co	chemical is like ystems and safe o not eat, drink o inated clothing b operation of a fa ontrols, proper p		the work- review of quipment,
			industrial hygi		medical surveillance	

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	off-white

according to GB/T 16483 and GB/T 17519



## Alendronate / Vitamin D Formulation

Versior 5.10	n Revision Date: 2020/03/23		S Number: 043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
00	dour Threshold	:	No data available	9
p⊦	I	:	No data available	9
M	elting point/freezing point	:	No data available	)
	tial boiling point and boiling nge	:	No data available	
Fla	ash point	:	Not applicable	
E١	aporation rate	:	Not applicable	
Fla	ammability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.
Fla	ammability (liquids)	:	No data available	)
	oper explosion limit / Upper mmability limit	:	No data available	
	wer explosion limit / Lower mmability limit	:	No data available	
Va	pour pressure	:	Not applicable	
Re	elative vapour density	:	Not applicable	
Re	elative density	:	No data available	)
De	ensity	:	No data available	)
So	lubility(ies) Water solubility	:	No data available	
	ntition coefficient: n- tanol/water	:	Not applicable	
	ito-ignition temperature	:	No data available	)
De	ecomposition temperature	:	No data available	)
Vi	scosity Viscosity, kinematic	:	Not applicable	
E>	plosive properties	:	Not explosive	
O	kidizing properties	:	The substance of	r mixture is not classified as oxidizing.
Pa	irticle size	:	No data available	)

### 10. STABILITY AND REACTIVITY



Version 5.10	Revision Date: 2020/03/23		S Number: 043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
	tivity nical stability ibility of hazardous reac-	:	Stable under no May form explose dling or other m	sive dust-air mixture during processing, han-
Incor	litions to avoid npatible materials irdous decomposition ucts	:	Heat, flames an Avoid dust form Oxidizing agent No hazardous d	ation.
11. TOXIO	COLOGICAL INFORMAT		1	
Expo	sure routes	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity			
	nful if swallowed.			
Prod Acute	e oral toxicity	:	Acute toxicity est Method: Calculat	timate: 1,965 mg/kg tion method
<u>Com</u>	ponents:			
Cellu	llose:			
Acute	e oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere	h
Acute	e dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg
Alen	dronate:			
-	e oral toxicity	:	LD50 (Rat): 552	- 626 mg/kg
			LD50 (Mouse): 9	66 - 1,280 mg/kg
Acute	e inhalation toxicity	:	Remarks: No dat	a available
Acute	e dermal toxicity	:	Remarks: No dat	a available
Colo	calciferol:			
	e oral toxicity	:	LD50 (Rat, male	): 35 mg/kg
Acute	e inhalation toxicity	:	Acute toxicity est Exposure time: 4 Test atmosphere Method: Expert j	h : dust/mist
			8 / 17	

according to GB/T 16483 and GB/T 17519

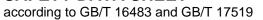


Version 5.10	Revision Date: 2020/03/23		DS Number: 043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
Acu	te dermal toxicity	:	Acute toxicity esti Method: Expert ju	
	n corrosion/irritation ses skin irritation.			
Con	nponents:			
Alei	ndronate:			
	cies narks	:	Rabbit Severe skin irritat	on
	i <b>ous eye damage/eye irr</b> ses serious eye damage.		ion	
Con	nponents:			
Ale	ndronate:			
Spe Res	cies ult	:	Rabbit Severe irritation	
Col	ecalciferol:			
Spe Res	cies ult	:	Rabbit No eye irritation	
Res	piratory or skin sensitis	atio	on	
-	n sensitisation classified based on availa	able	information.	
	piratory sensitisation			
	classified based on availa	able	information.	
	nponents:			
	ndronate: narks	:	No data available	
Tes Exp	ecalciferol: t Type osure routes cies ult		Maurer optimisation Skin contact Guinea pig negative	on test
	m cell mutagenicity classified based on availa	able	information.	
<u>Cor</u>	nponents:			
	ulose: notoxicity in vitro	:	Test Type: Bacter	ial reverse mutation assay (AMES)

according to GB/T 16483 and GB/T 17519



Version 5.10	Revision Date: 2020/03/23	SDS Number: 22043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
		Result: negat	ive
		Test Type: In Result: negat	vitro mammalian cell gene mutation test ive
Geno	toxicity in vivo	cytogenetic a Species: Mou	use oute: Ingestion
Alend	dronate:		
Geno	toxicity in vitro		kaline elution assay rat hepatocytes ive
			acterial reverse mutation assay (AMES) ivation: with and without metabolic activation ive
		Test Type: In Result: negat	vitro mammalian cell gene mutation test ive
			hromosomal aberration Chinese hamster ovary cells ocal
Geno	toxicity in vivo	: Test Type: Cl Species: Mou Result: negat	
Coleo	calciferol:		
Geno	toxicity in vitro		acterial reverse mutation assay (AMES) D Test Guideline 471 ocal
			vitro mammalian cell gene mutation test D Test Guideline 476 ive
			hromosome aberration test in vitro D Test Guideline 473 ive
Geno	toxicity in vivo	cytogenetic a Species: Rat Application R	oute: Ingestion D Test Guideline 474
		Test Type: In Species: Rat	vivo mammalian alkaline comet assay





10	Revision Date: 2020/03/23		OS Number: 043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
			Application Ro Result: positive	
	cell mutagenicity -	:	Weight of evide cell mutagen.	ence does not support classification as a germ
	nogenicity assified based on avai	ilable	information.	
<u>Comp</u>	oonents:			
	es cation Route sure time	:	Rat Ingestion 72 weeks negative	
Along	dronate:			
Speci Applic Expos	es cation Route sure time		Rat, male Oral 2 Years 1 mg/kg body v 3.75 mg/kg body	
Rema	et Organs arks	:	Thyroid The mechanisr mans.	m or mode of action may not be relevant in hu
Popr	aduativa taviaitu			
Suspe	oductive toxicity ected of damaging the conents:	unbo	rn child.	
Suspe	ected of damaging the conents:	unbo	rn child.	
Suspe <u>Comp</u> Cellul	ected of damaging the conents:	unbo :		
Suspe <u>Comr</u> Cellul Effect	ected of damaging the conents: lose:	unbo : :	Test Type: One Species: Rat Application Ro Result: negativ	ute: Ingestion re tility/early embryonic development ute: Ingestion
Suspe <u>Comr</u> Cellul Effect Effect ment	ected of damaging the <u>conents:</u> lose: is on fertility	unbo :	Test Type: One Species: Rat Application Ro Result: negativ Test Type: Fer Species: Rat Application Ro	ute: Ingestion re tility/early embryonic development ute: Ingestion
Suspe Comp Cellul Effect Effect ment	ected of damaging the <u>conents:</u> lose: is on fertility is on foetal develop-	unbo : :	Test Type: One Species: Rat Application Ro Result: negativ Test Type: Fer Species: Rat Application Ro Result: negativ Test Type: Fer Species: Rat, r Application Ro Fertility: NOAE	ute: Ingestion re tility/early embryonic development ute: Ingestion re tility nale and female

according to GB/T 16483 and GB/T 17519



rsion 0	Revision Date: 2020/03/23		9S Number: 043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
			Symptoms: Red weight, Skeletal	Toxicity: LOAEL: 1 - 15 mg/kg body weight uced number of viable fetuses, Reduced body malformations oxic effects and adverse effects on the off-
			Test Type: Deve Species: Rabbit Application Rou Developmental Result: No adve	, female te: Oral Toxicity: NOAEL: 40 mg/kg body weight
Repro sessn	oductive toxicity - As- nent	:	Some evidence animal experime	of adverse effects on development, based or ents.
	- single exposure cause respiratory irrita	tion.		
<u>Com</u>	oonents:			
Asses STOT	dronate: ssment - repeated exposure cause damage to orga		May cause resp	
Asses STOT May c <u>Comp</u> Alenc Targe	ssment	ins thro	bugh prolonged c Bone, Stomach,	r repeated exposure. Kidney
Asses STOT May o Comp Alenc Targe Asses	<b>- repeated exposure</b> cause damage to orga <b>conents:</b> <b>dronate:</b> et Organs	ins thro	bugh prolonged c Bone, Stomach, May cause dam	r repeated exposure. Kidney
Asses STOT May o Comp Alend Targe Asses Coled Expos Targe	<b>- repeated exposure</b> cause damage to orga <u>conents:</u> dronate: et Organs ssment	ins thro	bugh prolonged c Bone, Stomach, May cause dam exposure. Ingestion Kidney, Blood, E Shown to produ	r repeated exposure. Kidney age to organs through prolonged or repeated
Asses STOT May o Comp Alend Targe Asses Coled Expos Targe Asses	- repeated exposure cause damage to orga <u>conents:</u> dronate: et Organs ssment calciferol: sure routes et Organs	ins thro	bugh prolonged c Bone, Stomach, May cause dam exposure. Ingestion Kidney, Blood, E Shown to produ	r repeated exposure. Kidney age to organs through prolonged or repeated Bone ce significant health effects in animals at con-
Asses STOT May o Comp Alend Targe Asses Coled Expos Targe Asses Repe	- repeated exposure cause damage to orga <u>conents:</u> dronate: et Organs ssment calciferol: sure routes et Organs ssment	ins thro	bugh prolonged c Bone, Stomach, May cause dam exposure. Ingestion Kidney, Blood, E Shown to produ	r repeated exposure. Kidney age to organs through prolonged or repeated Bone ce significant health effects in animals at con-
Asses STOT May o Comp Alend Targe Asses Coled Expos Targe Asses Repe	- repeated exposure cause damage to orga conents: dronate: et Organs ssment calciferol: sure routes et Organs ssment ated dose toxicity conents:	ins thro	bugh prolonged c Bone, Stomach, May cause dam exposure. Ingestion Kidney, Blood, E Shown to produ	r repeated exposure. Kidney age to organs through prolonged or repeated Bone ce significant health effects in animals at con-
Asses STOT May of Comp Alend Targe Asses Coled Expos Targe Asses Repe Comp Cellu Speci NOAE Applio	<ul> <li>repeated exposure cause damage to orga ponents:</li> <li>dronate:</li> <li>dronate:</li> <li>dronate:</li> <li>organs</li> <li>ssment</li> </ul>	ins thro	bugh prolonged c Bone, Stomach, May cause dam exposure. Ingestion Kidney, Blood, E Shown to produ	r repeated exposure. Kidney age to organs through prolonged or repeated Bone ce significant health effects in animals at con-
Asses STOT May o Comp Alend Targe Asses Coled Expos Targe Asses Repe Comp Cellu Speci NOAE Applic Expos	<ul> <li>repeated exposure cause damage to orga conents:</li> <li>dronate:</li> <li></li></ul>	ins thro	Bone, Stomach, May cause dam exposure. Ingestion Kidney, Blood, E Shown to produ centrations of 10 Rat >= 9,000 mg/kg Ingestion	r repeated exposure. Kidney age to organs through prolonged or repeated Bone ce significant health effects in animals at con-

according to GB/T 16483 and GB/T 17519



## Alendronate / Vitamin D Formulation

Version 5.10	Revision Date: 2020/03/23	SDS Number: 22043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
Expo		2.5 mg/kg > 2.5 mg/kg Intravenous 53 Weeks Stomach	
Expo		: Dog : 0.01 mg/kg : Intravenous : 3 yr : Stomach, Bone	, Kidney
Expo	EL	: Dog : 2 mg/kg : 4 mg/kg : Oral : 53 Weeks : Kidney	
Speci NOAI LOAE Applic	EL EL cation Route sure time	: Rat : 0.06 mg/kg : 0.3 mg/kg : Ingestion : 90 Days : OECD Test Gu	ideline 408
Not c <u>Com</u> Alene	ration toxicity lassified based on ava ponents: dronate: pplicable	ailable information.	
	rience with human e	xposure	
Alend Inhala Skin o	contact contact	: Symptoms: Sev : Symptoms: Sev	piratory tract irritation vere irritation, skin blistering vere irritation strointestinal disturbance, musculoskeletal pain
		ON	
	oxicity ponents:		

Cellulose:

according to GB/T 16483 and GB/T 17519



Version 5.10	Revision Date: 2020/03/23	-	0S Number: 043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
Toxici	ty to fish	:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials
Alend	Ironate:			
Toxici	ty to fish	:	LC50 (Pimephale Exposure time: 96 Method: OECD To	
			LC50 (Oncorhync Exposure time: 96 Method: FDA 4.17	
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
Toxici plants	ty to algae/aquatic	:	ErC50 (Pseudokir mg/l Exposure time: 72 Method: OECD Te	
			NOEC (Pseudokin Exposure time: 72 Method: OECD Te	
Toxici icity)	ty to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te	
			LOEC (Pimephale Exposure time: 32 Method: OECD Te	
	ty to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD To	
Colec	alciferol:			
Toxici	ty to fish	:	LL50 (Danio rerio Exposure time: 96 Method: OECD Te	
	ty to daphnia and other ic invertebrates	:	EL50 (Daphnia m Exposure time: 48 Method: OECD Te	
Toxici plants	ty to algae/aquatic	:	EL50 (Scenedesn 100 mg/l Exposure time: 96 Method: OECD Te	

according to GB/T 16483 and GB/T 17519



## Alendronate / Vitamin D Formulation

/ersion 5.10	Revision Date: 2020/03/23	-	OS Number: 043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15
Persi	stence and degradab	oility		
Com	ponents:			
Cellu	lose:			
Biode	egradability	:	Result: Readily	biodegradable.
Alend	dronate:			
Biode	egradability	:	Result: Readily Biodegradation Exposure time:	
Stabi	lity in water	:		alf life (DT50): 375 d 9 Test Guideline 111
Cole	calciferol:			
Biode	egradability	:	Biodegradation Exposure time:	
Bioa	ccumulative potentia	I		
Com	ponents:			
Partit	<b>dronate:</b> ion coefficient: n- iol/water	:	log Pow: -1.73	
Cole	calciferol:			
	ion coefficient: n- ol/water	:	log Pow: > 6.2 Method: OECD	Test Guideline 107
Mobi	lity in soil			
No da	ata available			
	r adverse effects			
	ata available			
3. DISPC	SAL CONSIDERATIO	JNS		
Dispo	osal methods			
	e from residues aminated packaging	:	Empty containe	ccordance with local regulations. ers should be taken to an approved waste han

#### 14. TRANSPORT INFORMATION

#### International Regulations

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

according to GB/T 16483 and GB/T 17519



## Alendronate / Vitamin D Formulation

Version 5.10	Revision Date: 2020/03/23	SDS Number: 22043-00016	Date of last issue: 2019/09/13 Date of first issue: 2014/10/15						
<b>UNR</b> Not re	<b>TDG</b> egulated as a dangero	us good							
	IATA-DGR Not regulated as a dangerous good								
	G-Code egulated as a dangero	us good							
	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable for product as supplied.								
Natio	onal Regulations								
	944/12268 egulated as a dangero	us good							
-	Special precautions for user Not applicable								
15. REGU	15. REGULATORY INFORMATION								
	National regulatory information Law on the Prevention and Control of Occupational Diseases								
The of AICS	• •	roduct are reported : not determine	<b>in the following inventories:</b> d						

DSL	:	not determined
IECSC	:	not determined

### **16. OTHER INFORMATION**

Further information Sources of key data used to compile the 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/
Date format Full text of other abbreviation		yyyy/mm/dd
ACGIH GBZ 2.1-2007		USA. ACGIH Threshold Limit Values (TLV) Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
ACGIH / TWA GBZ 2.1-2007 / PC-TWA		8-hour, time-weighted average Permissible concentration - time weighted average

AICS - Australian Inventory of Chemical Substances; 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



## Alendronate / Vitamin D Formulation

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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

#### Disclaimer

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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