

Version 6.2	Revision Date: 23.07.2024		S Number: 2511-00012		sue: 25.03.2024 sue: 08.05.2020	
Section 1	: Identification					
Produ	uct name	:	Altrenogest (0.22	2%) Formulation	1	
Othe	r means of identification	:	REGUMATE (A0	04536)		
Manu	ufacturer or supplier's d	etai	ils			
Com	pany		MSD			
Addre	Address		33 Whakatiki Street - Private Bag 908 Upper Hutt - New Zealand			
Telep	bhone	:	0800 800 543			
Emer	rgency telephone number	:	0800 764 766 (08 CHEMCALL)	800 POISON)	0800 243 622 (0800	
E-ma	il address	:	EHSDATASTEW	/ARD@msd.cor	n	
Reco	ommended use of the ch	em	ical and restriction	ons on use		
	mmended use rictions on use	:	Veterinary produ Not applicable	ct		

Section 2: Hazard identification

GHS Classification Skin sensitisation	:	Category 1
Reproductive toxicity	:	Category 1
Hazardous to the aquatic environment - chronic hazard	:	Category 1
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H317 May cause an allergic skin reaction. H360 May damage fertility or the unborn child. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	Prevention:



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		P261 Avoid broken P272 Contamin the workplace. P273 Avoid rel	lease to the environment. otective gloves/ protective clothing/ eye protec-				
		P308 + P313 I attention.					
		Storage: P405 Store loc	sked up.				
		Disposal: P501 Dispose of contents/ container to an approved wa disposal plant.					
•	r hazards which do r known.	not result in classifica	tion				

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Benzyl alcohol	100-51-6	>= 1 -< 10
altrenogest	850-52-2	>= 0.1 -< 0.25

Section 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 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	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting.



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and dela <u>y</u> Prote	t important symptoms effects, both acute and yed ection of first-aiders is to physician	:	May cause an all May damage fert First Aid respond and use the reco when the potentia	ntion. oughly with water. ergic skin reaction. ility or the unborn child. ers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8). ically and supportively.
		•		
Section	5: Fire-fighting measure	S		
Unsu medi Spec	cific hazards during fire-	::	Water spray Alcohol-resistant Carbon dioxide (0 Dry chemical None known. Exposure to com	
fighti Haza ucts	ardous combustion prod-	:	Carbon oxides	
Spec ods	Specific extinguishing meth- ods		cumstances and Use water spray Remove undama so.	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do
for fi	cial protective equipment refighters chem Code	:		e, wear self-contained breathing apparatus. tective equipment.
Section 6	3: Accidental release me	eas	ures	
tive e	onal precautions, protec- equipment and emer- cy procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t recommendations (see section 8).
Envi	ronmental precautions	:	Prevent spreadin barriers). Retain and dispo	eakage or spillage if safe to do so. g over a wide area (e.g. by containment or oil se of contaminated wash water. should be advised if significant spillages
Moth	oods and materials for		Soak up with iner	t absorbent material

Methods and materials for	:	Soak up with inert absorbent material.
containment and cleaning up		For large spills, provide dyking or other appropriate contain-
		ment to keep material from spreading. If dyked material can
		be pumped, store recovered material in appropriate container.
		Clean up remaining materials from spill with suitable absor-



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		posal of this ma employed in the mine which regu Sections 13 and	al regulations may apply to releases and dis- terial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. I 15 of this SDS provide information regarding national requirements.
Section 7:	Handling and storag	9	
Techr	nical measures		g measures under EXPOSURE ERSONAL PROTECTION section.
Local/	Total ventilation		ilation is unavailable, use with local exhaust
Advic	e on safe handling	: Do not get on sl Do not breathe Do not swallow. Avoid contact w Handle in accor practice, based sessment Keep container	vapours or spray mist. ith eyes. dance with good industrial hygiene and safety on the results of the workplace exposure as-
Hygie	ne measures	flushing system place. When using do Wash contamin The effective op engineering cor appropriate deg	hemical is likely during typical use, provide eye s and safety showers close to the working not eat, drink or smoke. ated clothing before re-use. beration of a facility should include review of ntrols, proper personal protective equipment, owning and decontamination procedures, ne monitoring, medical surveillance and the rative controls
Condi	tions for safe storage	: Keep in properly Keep tightly close	y labelled containers.
Mater	ials to avoid		h the following product types:

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
altrenogest	850-52-2	TWA	1 µg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm²	Internal



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Engineering measures			 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the poten- tial exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops. 				
Pers	onal protective equip	ment					
Respiratory protection Filter type		: If su or	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Combined particulates and organic vapour type				
	I protection		homical register	at aloues			
IVI	aterial	: 0	hemical-resistar	it gloves			
	Remarks Eye protection Skin and body protection		the work enviror ists or aerosols, lear a faceshield otential for direc	gloving. ses with side shields or goggles. nment or activity involves dusty conditions, wear the appropriate goggles. d or other full face protection if there is a t contact to the face with dusts, mists, or			
Skin			sk being perforr psable suits) to a	arments should be used based upon the ned (e.g., sleevelets, apron, gauntlets, dis- avoid exposed skin surfaces. legowning techniques to remove potentially			

Section 9: Physical and chemical properties

Appearance	:	liquid
Colour	:	No data available
Odour	:	odourless
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available

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	Evapor	ation rate	:	No data available	
	Flamm	ability (solid, gas)	:	Not applicable	
	Flamm	ability (liquids)	:	No data available	
		explosion limit / Upper ability limit	:	No data available	
		explosion limit / Lower ability limit	:	No data available	
	Vapour	pressure	:	No data available	
	Relativ	e vapour density	:	No data available	
	Relativ	e density	:	No data available	
	Density	/	:	No data available	
	Solubili Wat	ity(ies) er solubility	:	No data available	
		n coefficient: n-	:	No data available	
	octanol Auto-ig	nition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty cosity, kinematic	:	No data available	
	Explosi	ive properties	:	Not explosive	
		ng properties	:		mixture is not classified as oxidizing.
		llar weight	:	No data available	
	Particle	e characteristics e size	:	No data available	

Section 10: Stability and reactivity

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition	:	None known. Oxidizing agents No hazardous decomposition products are known.



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produ	icts			
ection 1	1: Toxicological info	rmation		
Expo	sure routes	Ingest	contact	
	e toxicity lassified based on ava	ilable informa	ation.	
Prod	uct:			
	e oral toxicity			stimate: > 2,000 mg/kg stion method
Acute	inhalation toxicity	Expos Test a	sure time: atmosphere	stimate: > 5 mg/l 4 h e: dust/mist ation method
Acute	e dermal toxicity			stimate: > 2,000 mg/kg ation method
<u>Com</u>	ponents:			
Benz	yl alcohol:			
	e oral toxicity	: LD50	(Rat): 1,62	20 mg/kg
Acute	inhalation toxicity	Expos Test a		
Acute	e dermal toxicity	Metho	od: Expert	stimate: 1,100 mg/kg judgement d on national or regional regulation.
altrer	nogest:			
Acute	e oral toxicity	: LD50	(Rat): 177	mg/kg
		LD50	(Dog): 400) mg/kg
	corrosion/irritation lassified based on ava	ilable informa	ation.	
<u>Com</u>	ponents:			
Benz	yl alcohol:			
Speci Metho		: Rabbi : OECD		deline 404





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	Result		:	No skin irritation	
		s eye damage/eye irr ssified based on availa			
	Compo	onents:			
	Benzy	l alcohol:			
	Specie	S	:	Rabbit	
	Result Method	ł	:	Irritation to eyes, OECD Test Guide	reversing within 21 days eline 405
	Respir	atory or skin sensitis	satio	on	
		ensitisation luse an allergic skin re	actio	on.	
		atory sensitisation ssified based on availa	able	information.	
	Compo	onents:			
	Benzy	l alcohol:			
	Assess Remar		:		lence of skin sensitisation in humans I or regional regulation.
	Chron	ic toxicity			
		cell mutagenicity ssified based on availa	able	information.	
	Compo	onents:			
	Benzy	l alcohol:			
	Genoto	oxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
	Genoto	oxicity in vivo	:	cytogenetic assay Species: Mouse	nalian erythrocyte micronucleus test (in vivo /) :: Intraperitoneal injection
	altrend	ogest:			
		oxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
				Test Type: Chron Result: negative	nosome aberration test in vitro
				Test Type: DNA c	lamage and repair, unscheduled DNA syn-



rsion 2	Revision Date: 23.07.2024	SDS Number: 5842511-00012	Date of last issue: 25.03.2024 Date of first issue: 08.05.2020
		thesis in mamn Result: negativ	nalian cells (in vitro) e
	nogenicity lassified based on avai	lable information.	
<u>Com</u>	oonents:		
Benz	yl alcohol:		
	cation Route sure time od	: Mouse : Ingestion : 103 weeks : OECD Test Gu : negative	ideline 451
•	oductive toxicity damage fertility or the ι	unborn child.	
<u>Com</u>	oonents:		
Benz	yl alcohol:		
Effect	ts on fertility	Species: Rat Application Rou Result: negativ	
Effect ment	ts on foetal develop-	: Test Type: Em Species: Mous Application Rou Result: negativ	ute: Ingestion
altrer	nogest:		
	ts on fertility	Species: Rat Application Rot Fertility: NOAE	p-generation reproduction toxicity study ute: Oral L: 0.016 mg/kg body weight on fertility, No effects on mating performanc
		Species: Monk Application Ro	
		-	

Not classified based on available information.



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	- repeated exposu		
Not cla	assified based on av	ailable information.	
<u>Comp</u>	onents:		
altren	ogest:		
	ure routes	: Oral	
	t Organs	: Immune system	
Asses	sment	: May cause dam exposure.	age to organs through prolonged or repeate
Expos	ure routes	: Oral	
Target	t Organs	: Pituitary gland	
Repea	ated dose toxicity		
<u>Comp</u>	onents:		
-	l alcohol:		
Specie		: Rat	
NOAE	L ation Route	: 1.072 mg/l : inhalation (dust	/mist/fuma)
	ure time	: 28 Days	mistrane
Metho		: OECD Test Gui	deline 412
altren	ogest:		
Specie		: Rat	
NOAE		: 0.06 mg/kg	
	ation Route	: Oral : 13 Weeks	
	ure time t Organs		n, male reproductive organs, female reprodu
raiget	Congano	tive organs, Adı	
Remai	rks	: Effects on fertili	
Specie		: Pig	
NOAE		: 0.004 mg/kg	
	ation Route	: Oral : 13 Weeks	
	ure time t Organs		ve organs, female reproductive organs
Remai		: Effects on fertili	
Specie		: Pig	
NOAE		: 0.002 mg/kg	
	ation Route	: Oral	
	ure time t Organs	: 1 yr : male reproducti	ve organs, Pituitary gland
Remai		: Effects on fertili	
Specie		: Horse	
	1	: 220 mg/kg	
LOAE	∟ ation Route	: Oral	



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	Remarl	ks	:	No significant adv	erse effects were reported
	-	tion toxicity ssified based on availa	ble	information.	
	Experie	ence with human exp	osı	ire	
	Compo	onents:			
	altrenc Inhalati Skin co Eye co	ion Intact	:	Symptoms: respir Symptoms: Skin i Symptoms: Eye ir	
Sect	tion 12:	Ecological information	on		
	Ecotox	kicity			
	Compo	onents:			
	-	alcohol: / to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): 460 mg/l 5 h
		/ to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
	Toxicity plants	/ to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD To	
				NOEC (Pseudokin mg/l Exposure time: 72 Method: OECD Te	
		/ to daphnia and other invertebrates (Chron- ity)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
	altrend	ogest:			
		/ to fish (Chronic tox-	:	NOEC (Danio reri Exposure time: 32 Method: OECD Te	o (zebra fish)): 0.0004 µg/l 2 d est Guideline 210
	M-Fact toxicity	or (Chronic aquatic)	:	100,000	



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Persi	istence and degradabi	lity		
Com	ponents:			
Benz	yl alcohol:			
Biode	egradability	Biodeg	Readily bi gradation: 9 ure time: 14	
Bioa	ccumulative potential			
Com	ponents:			
Benz	yl alcohol:			
	ion coefficient: n- ol/water	: log Pov	w: 1.05	
	nogest:			
	ion coefficient: n- ol/water	: log Pov	w: 3.78	
Mobi	lity in soil			
Com	ponents:			
altrei	nogest:			
	bution among environ- al compartments	: log Koo	c: 3.3	
Othe	r adverse effects			
No da	ata available			
ection 1	3: Disposal considera	tions		
Disp	osal methods			
Wast	e from residues			waste into sewer.
Conta	aminated packaging	: Empty dling si	containers ite for recyc	ordance with local regulations. should be taken to an approved waste han- cling or disposal. becified: Dispose of as unused product.
Section 1	4: Transport informati	on		
Inter	national Regulations			
	TDG umber er shipping name		ONMENTA	ALLY HAZARDOUS SUBSTANCE, LIQUID,
		N.O.S.	(tapet)	

(altrenogest) 9

:

: 111

: 9

Class

Labels

Packing group





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Env	ironmentally hazardous	:	yes	
UN/	A-DGR ID No. per shipping name	:		nazardous substance, liquid, n.o.s.
Lab Pac airc Pac ger	king group els king instruction (cargo		(altrenogest) 9 III Miscellaneous 964 964 yes	
UN	G-Code number per shipping name	:	UN 3082 ENVIRONMENTA N.O.S. (altrenogest)	ALLY HAZARDOUS SUBSTANCE, LIQUID,
Lab Em	king group	: : : : : : : : : : : : : : : : : : : :	9 III 9 F-A, S-F yes	
	n sport in bulk according applicable for product as	-		OL 73/78 and the IBC Code
	ional Regulations	Sup	pilou.	
UN	5 5433 number per shipping name	:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,
Lab Haz	king group	: :	(altrenogest) 9 III 9 3Z no	
The bas She	ed upon the properties of	pro the catio	unpackaged mater	r informational purposes only, and solely ial as it is described within this Safety Data ode of transportation, package sizes, and var-

Section 15: Regulatory information

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



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0.2	20.01.2024	3042311 00012	
HSN	O Approval Number		
HSR	002244 Liquid containi	ng 0.15 - 0.25% Altren	ogest
	able Exposure Limits (pplicable	(TEL)	
Envir	onmental Exposure Li	mits (EEL)	
Not a	pplicable		
HSW	Controls		
Track		nce not required.	s Substances) Regulations 2017, for further in-
The o	components of this p	roduct are reported in	n the following inventories:
AICS		: not determined	
DSL		: not determined	
IECS	С	: not determined	
Section 1	6: Other information		

Revision Date	:	23.07.2024
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 Agency, http://echa.europa.eu/
Date format	:	dd.mm.yyyy

Full text of other abbreviations

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

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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; 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.

NZ / EN