according to GB/T 16483 and GB/T 17519



Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/03/25
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1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Altrenogest (0.22%) Formulation				
Other means of identification	:	REGUMATE (A004536)				
Manufacturer or supplier's details						
Company	:	MSD				
Address	:	No. 485 Jing Tai Road Pu Tuo District - Shanghai - China 200331				
Telephone	:	+1-908-740-4000				
Emergency telephone number	:	86-571-87268110				
E-mail address	:	EHSDATASTEWARD@msd.com				
Recommended use of the ch	em	ical and restrictions on use				
Recommended use Restrictions on use	:	Veterinary product Not applicable				

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance Colour Odour	: :	liquid No data available odourless
Very toxic to aquatic life with lo	ong	lasting effects.
GHS Classification Long-term (chronic) aquatic hazard	:	Category 1
GHS label elements		
Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H410 Very toxic to aquatic life with long lasting effects.



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Precautionary statements

Prevention:

1

P273 Avoid release to the environment.

Response:

P391 Collect spillage.

Disposal:

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

Physical and chemical hazards

Not classified based on available information.

Health hazards

Not classified based on available information.

Environmental hazards

Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification

None known.

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

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

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	important symptoms ffects, both acute and ed	:	None known.		
	Protection of first-aiders		and use the reco	ers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8).	
Notes	Notes to physician		: Treat symptomatically and supportively.		
5. FIREFIC	GHTING MEASURES				
Suitable extinguishing media		:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical		
Unsui media	itable extinguishing	:	None known.		
Speci fightir	fic hazards during fire- ng	:		bustion products may be a hazard to health.	
Haza ucts	rdous combustion prod-	:	Carbon oxides		
Speci ods	fic extinguishing meth-	:	cumstances and Use water spray	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	
	al protective equipment efighters	:	Evacuate area. In the event of fir	e, wear self-contained breathing apparatus. tective equipment.	
6. ACCIDE	ENTAL RELEASE MEAS	SUI	RES		
tive e	onal precautions, protec- quipment and emer- / procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t recommendations (see section 8).	
Envir	onmental precautions	:	Prevent spreadin barriers). Retain and dispo	akage 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	
	ods and materials for inment and cleaning up	:	For large spills, p ment to keep ma be pumped, store Clean up remaini bent.	t absorbent material. rovide dyking or other appropriate contain- terial from spreading. If dyked material can recovered material in appropriate container. ng materials from spill with suitable absor- regulations may apply to releases and dis-	

according to GB/T 16483 and GB/T 17519



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		employ mine w Sectior	ed in the cleanup nich regulations	nis SDS provide information regarding
7. HAND	LING AND STORAGE			
Han	dling			
Tech	nnical measures			res under EXPOSURE
Loca	al/Total ventilation		ent ventilation is	unavailable, use with local exhaust
	ce on safe handling dance of contact	: Do not Do not Do not Avoid o Handle practice sessme Keep o Take o	 Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safe practice, based on the results of the workplace exposure as sessment Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment. 	
		. UNIUZI	9 490113	
	age ditions for safe storage erials to avoid	Keep ti Store ii Do not	 Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents 	
Pack	kaging material	: Unsuitable material: None known.		ne known.

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 informa	ation: Skin		
		Wipe limit	10 µg/100 cm ²	Internal

protect products, workers, and the environment. Essentially no open handling permitted.	Engineering measures	
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according to GB/T 16483 and GB/T 17519



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		cabinet, fur tial exists fo	n a laboratory, use a properly designed biosafety ne hood, or other containment device if the poten- or aerosolization. If this potential does not exist, r lined trays or benchtops.		
Pers	onal protective equip	ment			
	iratory protection	sure asses ommended	local exhaust ventilation is not available or expo- sment demonstrates exposures outside the rec- guidelines, use respiratory protection.		
Filter type Eye/face protection		: Wear safet If the work mists or ae Wear a fac	Combined particulates and organic vapour type Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols		
Skin	Skin and body protection		rm or laboratory coat. body garments should be used based upon the performed (e.g., sleevelets, apron, gauntlets, dis- its) to avoid exposed skin surfaces. briate degowning techniques to remove potentially ed clothing.		
Hand	protection	containinat			
M	aterial	: Chemical-r	esistant gloves		
	emarks ene measures	: If exposure eye flushing ing place. When using Wash conta The effectiv engineering appropriate industrial h	ouble gloving. to chemical is likely during typical use, provide g systems and safety showers close to the work- g do not eat, drink or smoke. aminated clothing before re-use. we operation of a facility should include review of g controls, proper personal protective equipment, e degowning and decontamination procedures, ygiene monitoring, medical surveillance and the inistrative controls.		

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

according to GB/T 16483 and GB/T 17519



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Initial	boiling point and boili	ng : No data avail	able

range	•	
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n- octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics Particle size	:	No data available

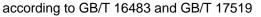
10. STABILITY AND REACTIVITY





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Reactivity Chemical stability Possibility of hazardous reac- tions Conditions to avoid Incompatible materials Hazardous decomposition products		:	Stable under nor Can react with st None known. Oxidizing agents	trong oxidizing agents.
11. TOXI	COLOGICAL INFORMA	ΓΙΟΙ	N	
Expo	osure routes	:	Inhalation Skin contact Ingestion Eye contact	
	t e toxicity classified based on availa	bla	information	
Proc		able	iniomation.	
·	e oral toxicity	:	Acute toxicity esti Method: Calculati	imate: > 5,000 mg/kg ion method
Acut	e inhalation toxicity	:	Acute toxicity estimate: > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method	
Com	ponents:			
Benz	zyl alcohol:			
Acut	e oral toxicity	:	LD50 (Rat): 1,620) mg/kg
Acut	e inhalation toxicity	:	Exposure time: 4 Test atmosphere	h
altre	nogest:			
Acut	e oral toxicity	:	LD50 (Rat): 177 r	ng/kg
			LD50 (Dog): 400	mg/kg
-	corrosion/irritation	able	information.	
Com	ponents:			
Benz Spec	zyl alcohol: cies	:	Rabbit	





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Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Benzyl alcohol:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days
Method	:	OECD Test Guideline 405

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Benzyl alcohol:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative
	-

Germ cell mutagenicity

Not classified based on available information.

Components:

Benzyl alcohol: Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES)
Genotoxicity in vivo :	Result: negative Test Type: Mammalian erythrocyte micronucleus test (in vivo
	cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative
altrenogest:	
Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosome aberration test in vitro

according to GB/T 16483 and GB/T 17519



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Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Benzyl alcohol:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	103 weeks
Method	:	OECD Test Guideline 451
Result	:	negative

Reproductive toxicity

Not classified based on available information.

Components:

Benzyl alcohol:	
Effects on fertility :	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal develop- : ment	Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative
altrenogest:	
Effects on fertility :	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: NOAEL: 0.016 mg/kg body weight Result: Effects on fertility, No effects on mating performance Test Type: Fertility/early embryonic development Species: Monkey, female Application Route: Oral Fertility: NOAEL: 0.004 mg/kg body weight
	· · · · · · · · · · · · · · · · · · ·
Reproductive toxicity - As- : sessment	Clear evidence of adverse effects on sexual function and fertil- ity, and/or on development, based on animal experiments

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STOT - single exposure

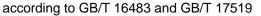
Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

altrenogest: Exposure routes Target Organs Assessment	:	Oral Immune system, Adrenal gland May cause damage to organs through prolonged or repeated exposure.
Exposure routes Target Organs	:	Oral Pituitary gland
Repeated dose toxicity		
Components:		
Benzyl alcohol: Species NOAEL Application Route Exposure time Method	::	Rat 1.072 mg/l inhalation (dust/mist/fume) 28 Days OECD Test Guideline 412
altrenogest:		
Species NOAEL Application Route Exposure time Target Organs Remarks	::	Rat 0.06 mg/kg Oral 13 Weeks Immune system, male reproductive organs, female reproduc- tive organs, Adrenal gland Effects on fertility
Species NOAEL Application Route Exposure time Target Organs Remarks	:	Pig 0.004 mg/kg Oral 13 Weeks male reproductive organs, female reproductive organs Effects on fertility
Species NOAEL Application Route Exposure time Target Organs Remarks	:	Pig 0.002 mg/kg Oral 1 yr male reproductive organs, Pituitary gland Effects on fertility





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Species LOAEL	: Horse : 220 mg/kg
Application Route	: Oral
Exposure time Remarks	86 DaysNo significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

altrenogest:

Inhalation	:	Symptoms: respiratory tract irritation
Skin contact	:	Symptoms: Skin irritation
Eye contact	:	Symptoms: Eye irritation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Benzyl alcohol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
altrenogest: Toxicity to fish (Chronic tox-	:	NOEC (Danio rerio (zebra fish)): 0.0004 µg/l
icity)	•	Exposure time: 32 d Method: OECD Test Guideline 210

Proper shipping name

according to GB/T 16483 and GB/T 17519



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	M-Fact toxicity	or (Chronic aquatic)	:	100,000	
I	Persist	tence and degradabili	ity		
<u>(</u>	Compo	onents:			
I	Benzyl	alcohol:			
I	Biodeg	radability	:	Result: Readily bi Biodegradation: 9 Exposure time: 14	92 - 96 %
I	Bioacc	umulative potential			
9	Compo	onents:			
I	Benzyl	alcohol:			
I	-	n coefficient: n-	:	log Pow: 1.05	
ä	altrenc	ogest:			
	Partitio octanol	n coefficient: n- /water	:	log Pow: 3.78	
I	Mobilit	y in soil			
<u>(</u>	Compo	onents:			
ä	altrenc	ogest:			
		ution among environ- compartments	:	log Koc: 3.3	
(Other a	adverse effects			
1	No data	a available			
13. D	ISPOS	SAL CONSIDERATION	IS		
1	Dispos	al methods			
	-	from residues	:	•	waste into sewer.
(Contan	ninated packaging			ordance with local regulations. should be taken to an approved waste han-
·	Contan	iniated packaging	dling site for recycling or disposal. If not otherwise specified: Dispose of as unused produc		
14. T	RANS	PORT INFORMATION			
I	Interna	tional Regulations			
I	UNRTE	DG			
l	UN nur	nber	:	UN 3082	

: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

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CI	lass		:	N.O.S. (altrenogest) 9	
	acking grou	ıр	:		
	abels	- 11	:	9	
Er	nvironment	ally hazardous	:	yes	
	TA-DGR				
-	N/ID No.		:	UN 3082	
Pr	roper shipp	ing name	:	Environmentally f (altrenogest)	nazardous substance, liquid, n.o.s.
-	lass		:	9	
	acking grou	ıp	:	III	
	abels		:	Miscellaneous	
air	rcraft)	uction (cargo	:	964	
	acking instr er aircraft)	ruction (passen-	:	964	
Ēr	nvironment	ally hazardous	:	yes	
	IDG-Code N number			UN 3082	
	roper shipp	ing name	:		ALLY HAZARDOUS SUBSTANCE, LIQUID,
		ing hame	•	N.O.S. (altrenogest)	
CI	lass			9	
-	acking grou	a	÷	Ĩ	
	abels	·F	:	9	
Er	mS Code		:	F-A, S-F	
Ma	arine pollut	ant	:	yes	

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

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number Proper shipping name	:	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (altrenogest)
Class	:	9
Packing group	:	
Labels	:	9
Marine pollutant	:	no

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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15. REGULATORY INFORMATION

National regulatory information Law on the Prevention and Control of Occupational Diseases Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

The components of this product are reported in the following inventories:

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

16. OTHER INFORMATION

Revision Date	:	2024/07/23
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	:	yyyy/mm/dd

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 Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect

SAFETY DATA SHEET according to GB/T 16483 and GB/T 17519



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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

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.

CN / EN