



Altrenogest (0.4%) Formulation

Version 4.0	Revision Date: 07/06/2024		DS Number: 1665-00023	Date of last issue: 05/16/2024 Date of first issue: 05/02/2016
	1. IDENTIFICATION			
	Product name Other means of identification		Altrenogest (0.4% REGUMATE ORA	AL PROGESTAGEN FOR PIGS (45680)
Manu	ufacturer or supplier's	deta	ails	
Company name of supplier Address Telephone Emergency telephone		:	126 E. Lincoln Av	enue sey U.S.A. 07065
	E-mail address		EHSDATASTEW	ARD@merck.com
Reco	ommended use of the c	hen	nical and restriction	ons on use
	mmended use rictions on use	:	Veterinary produc Not applicable	xt

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accord	dan	ce with the Hazardous Products Regulations
Reproductive toxicity	:	Category 1B

CHS label elements

GHS label elements Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H360 May damage fertility or the unborn child.
Precautionary Statements	:	Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P280 Wear protective gloves, protective clothing, eye protection and face protection.
		Response: P308 + P313 IF exposed or concerned: Get medical attention.
		Storage: P405 Store locked up.
		Disposal: P501 Dispose of contents and container to an approved waste disposal plant.





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Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Altrenogest	No data availa- ble	850-52-2	>= 0.1 - < 1 *

Actual concentration or concentration range is withheld as a trade secret

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	:	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.
Most important symptoms and effects, both acute and delayed	:	May damage fertility or the unborn child.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides

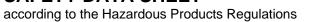


according to the Hazardous Products Regulations

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Specific extinguishing meth- ods		:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. Iged containers from fire area if it is safe to d
	ial protective equipment e-fighters	:		e, wear self-contained breathing apparatus. tective equipment.
SECTION	6. ACCIDENTAL RELE	ASI	EMEASURES	
tive e	onal precautions, protec- equipment and emer- y procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal nent recommendations (see section 8).
Envir	onmental precautions	:	Prevent spreadin oil barriers). Retain and dispo	eakage or spillage if safe to do so. g over a wide area (e.g., by containment or se of contaminated wash water. should be advised if significant spillages
	ods and materials for ainment and cleaning up	:	For large spills, p containment to ke can be pumped, container. Clean up remain absorbent. Local or national disposal of this m employed in the determine which Sections 13 and	rt absorbent material. provide diking or other appropriate seep material from spreading. If diked materia store recovered material in appropriate ing materials from spill with suitable regulations may apply to releases and naterial, as well as those materials and items cleanup of releases. You will need to regulations are applicable. 15 of this SDS provide information regarding ational requirements.

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe vapors or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed.





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Conditions for safe storage		 Take care to prevent spills, waste and minimize release to the environment. Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. 			
Materials to avoid		Strong oxidizing	ostances and mixtures		

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
Altrenogest	850-52-2	TWA	1 µg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm ²	Internal

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 potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.
Personal protective equipment	t
Respiratory protection : Filter type : Hand protection	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type
Material :	Chemical-resistant gloves
Remarks : Eye protection : Skin and body protection :	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. Work uniform or laboratory coat.
	Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

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Hygier	ne measures	contaminated c If exposure to c eye flushing sys working place. When using do Wash contamin The effective op engineering con appropriate deg	hemical is likely during typical use, provide stems and safety showers close to the 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, ne monitoring, medical surveillance and the

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor 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
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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available

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octar Autoi Deco Visco	ion coefficient: n- ol/water gnition temperature mposition temperature sity scosity, kinematic	: No : No	data available data available data available data available	9	
Explo	sive properties	: No	t explosive		
Oxidi	zing properties	: Th	e substance o	r mixture is not class	ified as oxidizing.
	cular weight	: No	data available	e	
	cle characteristics cle size	: No	data available	9	

SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

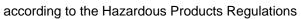
Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg
		Method: Calculation method

Components:

Altrenogest:

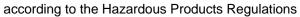
Acute oral toxicity	: LD50 (Rat): 177 mg/kg
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ersion .0	Revision Date: 07/06/2024	SDS Nu 641665		Date of last issue: 05/16/2024 Date of first issue: 05/02/2016
		LD5	0 (Dog): 40) mg/kg
	corrosion/irritation assified based on ava	ilable inforr	nation.	
	us eye damage/eye i assified based on ava		nation.	
Resp	iratory or skin sensit	tization		
-	sensitization assified based on ava	ilable inforr	nation.	
-	iratory sensitization assified based on ava	ilable inforr	nation.	
	cell mutagenicity assified based on ava	ilable inforr	nation.	
Comp	oonents:			
Altrer	nogest:			
Geno	toxicity in vitro		t Type: Bact ult: negative	erial reverse mutation assay (AMES)
			Type: Chro ult: negative	mosome aberration test in vitro
		thes	•••	damage and repair, unscheduled DNA syn- alian cells (in vitro)
	nogenicity assified based on ava	ilable inforr	nation.	
Repro	oductive toxicity			
May c	amage fertility or the	unborn chil	d.	
<u>Comp</u>	oonents:			
	nogest:	_		
Effect	s on fertility	Spe App Fert	cies: Rat lication Rou ility: NOAEL	generation reproduction toxicity study te: Oral .: 0.016 mg/kg body weight on fertility., No effects on mating performance.
		Test		lity/early embryonic development
		Арр	lication Rou	
Repro sessn	oductive toxicity - As- nent			of adverse effects on sexual function and n development, based on animal experiments



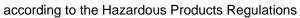


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STO	Γ-single exposure		
Not c	lassified based on av	ailable information	
	F-repeated exposure		
Not c	lassified based on av	allable information	
Com	ponents:		
Altre	nogest:		
	es of exposure	: Oral	
	et Organs		vstem, Adrenal gland
Asse	ssment	: May cause exposure.	e damage to organs through prolonged or repeate
	es of exposure	: Oral	a se al
Iarge	et Organs	: Pituitary gl	and
Repe	ated dose toxicity		
Com	ponents:		
Altre	nogest:		
Spec		: Rat	
NOA		: 0.06 mg/kg]
	cation Route	: Oral	
	sure time	: 13 Weeks	
Targe	et Organs		vstem, male reproductive organs, female reproductive
Rema	arks	: Effects on	s, Adrenal gland fertility.
IIenoo	ioo	· Dia	
Spec NOA		: Pig : 0.004 mg/l	(0
	cation Route	: 0:004 mg/	^y
	sure time	: 13 Weeks	
	et Organs		ductive organs, female reproductive organs
Rema	arks	: Effects on	fertility.
Spec		: Pig	
NOA		: 0.002 mg/	٨g
	cation Route	: Oral	
	sure time	: 1 y	ductive encours Dir Versionale et
	et Organs		ductive organs, Pituitary gland
Rema	aiks	: Effects on	ierunty.
Spec		: Horse	
LOAE		: 220 mg/kg	
Appli	cation Route	: Oral	
			ant adverse effects were reported
Expo Rema	sure time	: 86 Days	ant adverse effects were reported

Aspiration toxicity

Not classified based on available information.





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Expe	rience with human ex	oosi	ıre	
Com	oonents:			
Altre	nogest:			
Inhala		:		piratory tract irritation
	contact contact	:	Symptoms: Ski Symptoms: Eye	
SECTION	12. ECOLOGICAL INF	OR		
Ecoto	oxicity			
	oonents:			
	nogest: ity to fish (Chronic tox-	:	NOEC (Danio r	erio (zebra fish)): 0.0004 μg/l
icity)			Exposure time:	32 d
			Method: OECD	Test Guideline 210
Persi	stence and degradabi	lity		
	ata available	-		
Bioad	ccumulative potential			
<u>Com</u>	oonents:			
Altre	nogest:			
	ion coefficient: n-	:	log Pow: 3.78	
	ol/water			
Mobi	lity in soil			
<u>Com</u>	ponents:			
Altre	nogest:			
	bution among environ- al compartments	:	log Koc: 3.3	
Othe	r adverse effects			
No da	ata available			
SECTION	13. DISPOSAL CONSI	DEF	ATIONS	
Dispo	osal methods			
-	e from residues	:	Do not dispose	of waste into sewer.

Waste from residues	: Do not dispose of waste into sewer.
	Dispose of in accordance with local regulations.
Contaminated packaging	: Empty containers should be taken to an approved waste
	handling site for recycling or disposal.
	If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations





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UNR [.]	TDG			
UN n	umber	:	UN 3082	
Prope	er shipping name	:	ENVIRONMENT N.O.S. (altrenogest)	ALLY HAZARDOUS SUBSTANCE, LIQUID
Class	6	:	9	
Packi	ing group	:	111	
Labe		:	9	
Envir	onmentally hazardous	:	yes	
	-DGR			
UN/IE	D No.	:	UN 3082	
Prope	er shipping name	:	Environmentally (Altrenogest)	hazardous substance, liquid, n.o.s.
Class	6	:	9	
Packi	ing group	:		
Labe	-	:	Miscellaneous	
Packi aircra	ing instruction (cargo ift)	:	964	
	ing instruction (passen- ircraft)	:	964	
	onmentally hazardous	:	yes	
IMDO	G-Code			
UN n	umber	:	UN 3082	
Prope	er shipping name	:	ENVIRONMENT N.O.S. (Altrenogest)	ALLY HAZARDOUS SUBSTANCE, LIQUID
Class	3	•	9	
	, ing group	÷	Ĩ	
Labe		÷	9	
	Code		F-A, S-F	
	e pollutant	:	yes	

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

Not applicable for product as supplied.

Domestic regulation

TDG UN number Proper shipping name	:	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Altrenogest)
Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Altrenogest)

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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SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:							
AICS	:	not determined					
DSL	:	not determined					
IECSC	:	not determined					

SECTION 16. OTHER INFORMATION

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 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

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	:	07/06/2024

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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

CA / Z8