

Vers 6.2	sion	Revision Date: 2023/11/16		S Number: 05-00023	Date of last issue: 2023/09/29 Date of first issue: 2014/10/28			
1. P	1. PRODUCT AND COMPANY IDENTIFICATION							
	Product	name	:	Trenbolone / Estradiol LA Formulation				
	Manufa	cturer or supplier's d	letai	ls				
	Compar	ny	:	MSD				
	Address	8	:	126 E. Lincoln Av Rahway, New Jei	venue rsey U.S.A. 07065			
	Telepho	one	:	908-740-4000				
	Emerge	ncy telephone number	• :	1-908-423-6000				
	E-mail a	address	:	EHSDATASTEW	ARD@msd.com			
	Recom	mended use of the ch	nemi	cal and restrictio	ns on use			
		mended use	:	Veterinary produc	ct			
	Restrict	ions on use	:	Not applicable				
2. H	2. HAZARDS IDENTIFICATION							
	GHS CI	assification						
	Carcino	genicity	:	Category 1A				
	Reprod	uctive toxicity	:	Category 1A				
		: target organ toxicity - d exposure	:	Category 1 (Liver	, Bone, Blood, Endocrine system)			

Specific target organ toxicity - repeated exposure (Oral)		Category 1 (Endocrine system, Blood)
Long-term (chronic) aquatic	:	Category 1

:

:

:

Danger

#### **GHS** label elements

Hazard pictograms

Signal word

hazard

Hazard statements

H350 May cause cancer. H360FD May damage fertility. May damage the unborn child. H372 Causes damage to organs (Liver, Bone, Blood, Endo-



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		H372 Causes through prolor	through prolonged or repeated exposure. damage to organs (Endocrine system, Blood) nged or repeated exposure if swallowed. ic to aquatic life with long lasting effects.
Preca	utionary statements	P202 Do not h and understoc P260 Do not b P264 Wash sk P270 Do not e P273 Avoid re	vereathe dust. kin thoroughly after handling. eat, drink or smoke when using this product. lease to the environment. otective gloves/ protective clothing/ eye protec-
		<b>Response:</b> P308 + P313   attention. P391 Collect s	F exposed or concerned: Get medical advice/
		<b>Storage:</b> P405 Store loo	cked up.
		<b>Disposal:</b> P501 Dispose disposal plant.	of contents/ container to an approved waste
Dust	r <b>hazards which do no</b> contact with the eyes c act with dust can cause	an lead to mechanica	l irritation.
			ssing, handling or other means.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
17β-hydroxyestra-4,9,11-trien-3-one 17-acetate	10161-34-9	>= 60 -<= 100
Estradiol	50-28-2	>= 2.5 -< 10
Magnesium stearate	557-04-0	< 10

### 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.



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	In case	of skin contact	:	of water.	t, immediately flush skin with soap and plenty nated clothing and shoes. tion.			
	In case	of eye contact	:	Thoroughly clean If in eyes, rinse w	shoes before reuse. ell with water.			
	If swalle	owed	:		tion if irritation develops and persists. NOT induce vomiting. tion.			
		nportant symptoms ects, both acute and d	:	May cause cance May damage ferti Causes damage t exposure.	oughly with water. r. lity. May damage the unborn child. to organs through prolonged or repeated can cause mechanical irritation or drying of			
	Protection of first-aiders		:	<ul> <li>Dust contact with the eyes can lead to mechanical irritation.</li> <li>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).</li> <li>Treat symptomatically and supportively.</li> </ul>				
5. FI		o physician	•					
	Suitable	e extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical				
	Unsuita media	ble extinguishing	:	None known.				
	Specific fighting	c hazards during fire-	:	concentrations, and potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. pustion products may be a hazard to health.			
	Hazard ucts	ous combustion prod-	:	Carbon oxides Metal oxides				
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t Remove undama so.	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			
	Special for firefi	protective equipment ghters	:		e, wear self-contained breathing apparatus. tective equipment.			

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :	Use personal protective equipment.
tive equipment and emer-	Follow safe handling advice (see section 7) and personal pro-



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gen	cy procedures		tective equipment	recommendations (see section 8).		
Env	rironmental precautions	:	<ul> <li>Avoid release to the environment.</li> <li>Prevent further leakage or spillage if safe to do so.</li> <li>Retain and dispose of contaminated wash water.</li> <li>Local authorities should be advised if significant spillage cannot be contained.</li> </ul>			
	hods and materials for tainment and cleaning up	:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the atr Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces		
7. HAND	LING AND STORAGE					
Тес	hnical measures	:	causing an explose Provide adequate	precautions, such as electrical grounding		
Loc	al/Total ventilation	:	and bonding, or in If sufficient ventila ventilation.	tion is unavailable, use with local exhaust		
Adv	rice on safe handling	:	Do not get on skir Do not breathe du Do not swallow. Avoid contact with Wash skin thoroug Handle in accorda practice, based or sessment Keep container tig Minimize dust ger Keep container cle Keep away from h Take precautiona Do not eat, drink o Take care to prev	ist. n eyes. ghly after handling. ance with good industrial hygiene and safety n the results of the workplace exposure as-		
Cor	nditions for safe storage	:	Store locked up. Keep tightly close			
Mat	erials to avoid	:		ce with the particular national regulations. the following product types: gents		



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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis			
17β-hydroxyestra-4,9,11-trien- 3-one 17-acetate	10161-34-9	TWA	0.2 µg/m3 (OEB 5)	Internal			
		Wipe limit	2 µg/100 cm <sup>2</sup>	Internal			
Estradiol	50-28-2	TWA	0.05 μg/m3 (OEB 5)	Internal			
	Further information: Skin						
		Wipe limit	0.5 µg/100 cm <sup>2</sup>	Internal			
Magnesium stearate	557-04-0	NAB	10 mg/m3	ID OEL			
		ation: Not classified as carcinogenic to humans. Not o classify these materials as carcinogenic to hu- als					
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH			
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH			

#### Components with workplace control parameters

Engineering measures	Use closed processing systems or containment technologie to control at source (e.g., glove boxes/isolators) and to pre- vent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment tech nology designed to prevent leakage of compounds into the workplace.	
Personal protective equipme		
Respiratory protection Filter type Hand protection	e assessment demon	t ventilation is not available or expo- strates exposures outside the rec- se respiratory protection.
Material	emical-resistant glove	:S
Remarks Eye protection	nsider double gloving ar safety glasses with	n side shields or goggles.



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Skin and body protection		mists or aeroso Wear a facesh potential for din aerosols. : Work uniform of Additional body task being perf posable suits)	rironment or activity involves dusty conditions, ols, wear the appropriate goggles. ield or other full face protection if there is a rect contact to the face with dusts, mists, or or laboratory coat. y garments should be used based upon the formed (e.g., sleevelets, apron, gauntlets, dis- to avoid exposed skin surfaces. te degowning techniques to remove potentially clothing
Hygiene measures		: If exposure to e eye flushing sy ing place. When using do Wash contamin The effective o engineering co appropriate de industrial hygie	chemical is likely during typical use, provide ystems and safety showers close to the work- o not eat, drink or smoke. nated clothing before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the trative controls.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	No data available
Odour	:	No data available
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	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available



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Vapo	our pressure	:	No data available	9
Rela	tive vapour density	:	No data available	9
Rela	tive density	:	No data available	9
Dens	sity	:	No data available	e
	bility(ies) /ater solubility	:	No data available	e
	tion coefficient: n- nol/water	:	No data available	9
	-ignition temperature	:	No data available	9
Deco	mposition temperature	:	No data available	9
Visco V	osity iscosity, kinematic	:	No data available	9
Explo	osive properties	:	Not explosive	
	zing properties	:		r mixture is not classified as oxidizing.
Mole	cular weight		No data available	9
Parti	cle size	:	No data available	9

### **10. STABILITY AND REACTIVITY**

Reactivity Chemical stability Possibility of hazardous reac- tions	: :	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion
		Eye contact



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	e toxicity			
	assified based on availa	able	information.	
	oonents:			
-	ydroxyestra-4,9,11-trie			
Acute	oral toxicity	:	LD50 (Rat): > 5	,000 mg/kg
			LD50 (Mouse):	2,700 mg/kg
Estra	diol:			
Acute	oral toxicity	:	LD50 (Rat): > 2	,000 mg/kg
	toxicity (other routes of	:		
admin	istration)		Application Rou	ite: Subcutaneous
Magn	esium stearate:			
Acute	oral toxicity	:	LD50 (Rat): > 2	,000 mg/kg Test Guideline 423
				he substance or mixture has no acute oral to
			icity Remarks: Base	d on data from similar materials
_				
Acute	dermal toxicity	:	LD50 (Rabbit): Remarks: Base	> 2,000 mg/kg d on data from similar materials
Skin /	corrosion/irritation			
-	assified based on availa	able	information.	
	oonents:			
	esium stearate:			
Speci	es	:	Rabbit	
Resul		:	No skin irritation	
Rema	Irks	:	Based on data f	rom similar materials
	us eye damage/eye irr			
Not cl	assified based on availa	able	information.	
<u>Comp</u>	oonents:			
Estra				
Resul	t	:	No eye irritation	
Magn	esium stearate:			
Speci		:	Rabbit	
Resul		:	No eye irritation	i irom similar materials
Rema	IKS	•	Dased on data	TOTT SITURAL THALEHAIS



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### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

#### **Components:**

#### Estradiol:

Exposure routes	:	Skin contact
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitisation.
Result	:	negative

#### Magnesium stearate:

Test Type :	Maximisation Test
Exposure routes :	Skin contact
Species :	Guinea pig
Method :	OECD Test Guideline 406
Result :	negative
Remarks :	Based on data from similar materials

#### Germ cell mutagenicity

Not classified based on available information.

### Components:

### 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:

Genotoxicity in vitro	Test Type: Bacterial reverse mutation assay (AMES) Test system: Salmonella typhimurium Result: negative
	Test Type: Micronucleus test Test system: Chinese hamster fibroblasts Result: negative
Genotoxicity in vivo :	Test Type: Micronucleus test Species: Mouse Result: negative
	Test Type: Micronucleus test Species: Rat Result: negative
Germ cell mutagenicity - : Assessment	Weight of evidence does not support classification as a germ cell mutagen.
Estradiol: Genotoxicity in vitro :	Test Type: DNA damage and repair, unscheduled DNA syn-



ersion .2	Revision Date: 2023/11/16	SDS Number: 26105-00023	Date of last issue: 2023/09/29 Date of first issue: 2014/10/28
			nmalian cells (in vitro) mammalian cells
		Result: positi	
			hromosome aberration test in vitro mammalian cells ve
			nromosomal aberration mammalian cells ve
Genot	toxicity in vivo	: Test Type: C Species: Rat Cell type: Bo Result: negat	
		Test Type: C Species: Mou Cell type: Bou Result: negat	ne marrow
Magn	esium stearate:		
Genot	toxicity in vitro	Result: negat	vitro mammalian cell gene mutation test ive sed on data from similar materials
			nromosome aberration test in vitro D Test Guideline 473 ive
		Remarks: Ba	sed on data from similar materials
		Result: negat	acterial reverse mutation assay (AMES) ive sed on data from similar materials
	nogenicity ause cancer.		
-	oonents:		
17β-h	ydroxyestra-4,9,11-	trien-3-one 17-aceta	te:
Speci Applic	es cation Route	: Mouse, male : Oral	and female
Resul		: positive : Liver	
	ation Route	: Rat, male and : Oral	d female
Resul Targe	t t Organs	: positive : Pancreas	



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Carcir ment	nogenicity - Assess-	:	Limited eviden	ce of carcinogenicity in animal studies
Estra	diol:			
Specie	es	:	Mouse	
	ation Route	:	Ingestion	
•	sure time	:	24 Months	
LOAE Result		÷	100 µg/kg	
	t Organs	:	positive female reprodu	uctive organs
Specie		:	Rat	
	ation Route	:	Subcutaneous	
LOAE	sure time	:	13 weeks 20 mg/kg body	weight
Result		:	positive	weight
	t Organs	:	Endocrine syst	em
Carcir ment	nogenicity - Assess-	:	Positive evider	nce from human epidemiological studies
17β-h	<u>oonents:</u> ydroxyestra-4,9,11-tr	ien-3		
17β-h		ien-3	Test Type: Two Species: Rat Application Ro Fertility: LOAE	o-generation study
<b>17β-h</b> Effects	<b>ydroxyestra-4,9,11-tr</b> s on fertility	ien-3	Test Type: Two Species: Rat Application Ro Fertility: LOAE Result: Postim	o-generation study ute: Oral L: 0.18 mg/kg body weight plantation loss.
<b>17β-h</b> Effects	ydroxyestra-4,9,11-tr	ien-3	Test Type: Two Species: Rat Application Ro Fertility: LOAE Result: Postim Test Type: Em Species: Rat	o-generation study ute: Oral L: 0.18 mg/kg body weight plantation loss. bryo-foetal development
<b>17β-h</b> Effects	<b>ydroxyestra-4,9,11-tr</b> s on fertility	ien-3	Test Type: Two Species: Rat Application Ro Fertility: LOAE Result: Postim Test Type: Em Species: Rat Application Ro	o-generation study ute: Oral L: 0.18 mg/kg body weight plantation loss. bryo-foetal development ute: oral (feed)
<b>17β-h</b> Effects	<b>ydroxyestra-4,9,11-tr</b> s on fertility	ien-3	Test Type: Two Species: Rat Application Ro Fertility: LOAE Result: Postim Test Type: Em Species: Rat Application Ro Developmenta	o-generation study ute: Oral L: 0.18 mg/kg body weight plantation loss. bryo-foetal development ute: oral (feed)
<b>17β-h</b> Effects Effects ment	ydroxyestra-4,9,11-tr s on fertility s on foetal develop- oductive toxicity - As-	ien-3	Test Type: Two Species: Rat Application Ro Fertility: LOAE Result: Postim Test Type: Em Species: Rat Application Ro Developmenta Result: Malforr Some evidence fertility, based	o-generation study ute: Oral L: 0.18 mg/kg body weight plantation loss. bryo-foetal development ute: oral (feed) I Toxicity: LOAEL: 20 mg/kg body weight nations were observed. e of adverse effects on sexual function at on animal experiments., Some evidence
<b>17β-h</b> Effects ment	ydroxyestra-4,9,11-tr s on fertility s on foetal develop- oductive toxicity - As- nent	ien-3 : :	Test Type: Two Species: Rat Application Ro Fertility: LOAE Result: Postim Test Type: Em Species: Rat Application Ro Developmenta Result: Malforr Some evidence fertility, based adverse effects	o-generation study ute: Oral L: 0.18 mg/kg body weight plantation loss. bryo-foetal development ute: oral (feed) I Toxicity: LOAEL: 20 mg/kg body weight nations were observed. e of adverse effects on sexual function a on animal experiments., Some evidence
17β-h Effects ment Repro sessm	ydroxyestra-4,9,11-tr s on fertility s on foetal develop- oductive toxicity - As- nent	•ien-3 : :	Test Type: Two Species: Rat Application Ro Fertility: LOAE Result: Postim Test Type: Em Species: Rat Application Ro Developmenta Result: Malforr Some evidence fertility, based adverse effects ments. Test Type: One Species: Rat Application Ro Fertility: LOAE	o-generation study ute: Oral L: 0.18 mg/kg body weight plantation loss. bryo-foetal development ute: oral (feed) I Toxicity: LOAEL: 20 mg/kg body weight nations were observed. e of adverse effects on sexual function an on animal experiments., Some evidence s on development, based on animal expe e-generation reproduction toxicity study ute: Ingestion L: 0.5 mg/kg body weight
17β-h Effects ment Repro sessm	ydroxyestra-4,9,11-tr s on fertility s on foetal develop- oductive toxicity - As- nent	•ien-3 : :	Test Type: Two Species: Rat Application Ro Fertility: LOAE Result: Postim Test Type: Em Species: Rat Application Ro Developmenta Result: Malforr Some evidence fertility, based adverse effects ments. Test Type: On Species: Rat Application Ro Fertility: LOAE Result: Effects	<ul> <li>b-generation study</li> <li>ute: Oral</li> <li>L: 0.18 mg/kg body weight</li> <li>plantation loss.</li> <li>bryo-foetal development</li> <li>ute: oral (feed)</li> <li>I Toxicity: LOAEL: 20 mg/kg body weight nations were observed.</li> <li>e of adverse effects on sexual function at on animal experiments., Some evidence is on development, based on animal experiments on animal experiments.</li> <li>e-generation reproduction toxicity study</li> <li>ute: Ingestion</li> <li>L: 0.5 mg/kg body weight</li> </ul>



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		Fertility: LOA Result: Effect Test Type: Ty Species: Mou Application R	vo-generation study ise oute: Oral EL: 0.1 mg/kg body weight
Effect	ts on foetal develop-	Species: Mou Application R Teratogenicit Symptoms: M Result: positi Test Type: O Species: Rat Application R Teratogenicit Symptoms: R Result: positi	mbryo-foetal development use, female oute: Subcutaneous y: LOAEL: 4 mg/kg body weight falformations were observed. ve, Teratogenic effects ne-generation reproduction toxicity study oute: Subcutaneous y: LOAEL: 2.5 µg/kg body weight teduced body weight ve, Embryotoxic effects and adverse effects on were detected.
		Species: Rat Application R Development Symptoms: E number of via Result: Embr	mbryo-foetal development oute: Subcutaneous al Toxicity: LOAEL: 0.2 mg/kg body weight arly Resorptions / resorption rate, Reduced able fetuses, Reduced body weight yotoxic effects and adverse effects on the off- letected only at high maternally toxic doses
Repro sessr	oductive toxicity - As- nent	: May damage	fertility. May damage the unborn child.
-	<b>tesium stearate:</b> ts on fertility	reproduction/ Species: Rat Application R Method: OEC Result: negation	ombined repeated dose toxicity study with the developmental toxicity screening test oute: Ingestion CD Test Guideline 422 ive sed on data from similar materials
Effect ment	ts on foetal develop-	Species: Rat Application R Result: negation	mbryo-foetal development oute: Ingestion ive sed on data from similar materials



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### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Causes damage to organs (Liver, Bone, Blood, Endocrine system) through prolonged or repeated exposure.

Causes damage to organs (Endocrine system, Blood) through prolonged or repeated exposure if swallowed.

#### Components:

#### 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:

Exposure routes	:	Ingestion
Target Organs	:	Endocrine system, Blood
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

#### **Estradiol:**

Target Organs	:	Liver, Bone, Blood, Endocrine system
Assessment	:	Causes damage to organs through prolonged or repeated
		exposure.

#### **Repeated dose toxicity**

#### Components:

#### 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:

Species NOAEL LOAEL Exposure time Target Organs	:	Pig 0.004 mg/kg 0.08 mg/kg 14 Weeks Testis, Ovary, Liver, Uterus (including cervix)
Species NOAEL LOAEL Application Route Exposure time Target Organs		Rat 0.04 mg/kg 3.6 mg/kg Oral 23 Weeks Blood
Species NOAEL LOAEL Application Route Exposure time Target Organs		Monkey, female 0.01 mg/kg 0.04 mg/kg Oral 122 Days female reproductive organs
Species NOAEL LOAEL Application Route Exposure time		Monkey, male 0.002 mg/kg 0.04 mg/kg Oral 30 Days



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Targe	t Organs	: male reproduc	tive organs
Specie	es	: Rat	
NOAE		: 0.05 mg/kg	
LOAE	L	: 0.1 mg/kg	
	ation Route	: Oral	
	sure time	: 3 Months	
Targe	t Organs	: male reproduc	tive organs, Ovary, Uterus (including cervix)
Estra	diol:		
Specie	es	: Rat	
LOAE		: >= 0.17 mg/kg	
	ation Route	: Ingestion	
	sure time	: 90 d	
Targe	t Organs		nd, Ovary, Uterus (including cervix), Liver, Bo tem, Blood, Testis
Magn	esium stearate:		
Specie	es	: Rat	
NOAE		: > 100 mg/kg	
	ation Route	: Ingestion	
	sure time	: 90 Days	
Rema	rks	: Based on data	from similar materials
Aspira	ation toxicity		
Not cla	assified based on ava	ailable information.	
Exper	ience with human e	exposure	
<u>Comp</u>	oonents:		
-		trien-3-one 17-acetate	
Ingest	ion	: Symptoms: ma in libido	ale reproductive effects, gynecomastia, chang
Estra	diol:		
Inhala	tion		gling, Nose bleeding
	ontact		in irritation, Redness, pruritis
Ingest	ion		adache, Gastrointestinal disturbance, Dizzi-
			J, Diarrhoea, water retention, liver function
			jes in libido, breast tenderness, menstrual irre
		ularities	

### Ecotoxicity

### Components:

### 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:

Toxicity to fish (Chronic tox- : NOEC (Pimephales promelas (fathead minnow)): 0.000035



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i	icity)			mg/l	
				Exposure time: 21 Method: OECD Te	
	M-Factor (Chronic aquatic toxicity)		:	1,000	
I	Estradi	iol:			
-	Toxicity	v to fish	:	LC50 (Oryzias lati Exposure time: 96	pes (Japanese medaka)): 3.9 mg/l 3 h
		to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): 2.7 mg/l 3 h
	Toxicity to algae/aquatic plants		:	NOEC (Pseudokin mg/l Exposure time: 72 Method: OECD To	
					chneriella subcapitata (green algae)): > 1.7
	Toxicity icity)	to fish (Chronic tox-	:	NOEC (Oryzias la Exposure time: 16 Method: OECD Te	
i	aquatic	to daphnia and other invertebrates (Chron-	:	NOEC (Daphnia r Exposure time: 21	nagna (Water flea)): 0.2 mg/l d
I	ic toxici M-Facto toxicity)	or (Chronic aquatic	:	1,000	
		to microorganisms	:	EC50: > 100 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te	ation inhibition
				NOEC: 100 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te	ation inhibition
	Magne	sium stearate:			
	Toxicity		:	Exposure time: 48 Method: DIN 384	
		to daphnia and other invertebrates	:	EL50 (Daphnia m Exposure time: 47	agna (Water flea)): > 1 mg/l ′ h



rsion	Revision Date: 2023/11/16		S Number: 05-00023	Date of last issue: 2023/09/29 Date of first issue: 2014/10/28
			Method: Directive	Nater Accommodated Fraction e 67/548/EEC, Annex V, C.2. on data from similar materials limit of solubility
Toxici plants	ty to algae/aquatic	:	mg/l Exposure time: 72 Test substance: \ Method: OECD T Remarks: Based No toxicity at the NOELR (Pseudol mg/l Exposure time: 72 Test substance: \ Method: OECD T	Water Accommodated Fraction Test Guideline 201 on data from similar materials limit of solubility kirchneriella subcapitata (green algae)): > 1 2 h Water Accommodated Fraction Test Guideline 201
Toxici	ty to microorganisms	:	EC10 (Pseudomo Exposure time: 1) Test substance: \	on data from similar materials onas putida): > 100 mg/l 6 h Nater Accommodated Fraction on data from similar materials
Persi	stence and degradabi	ility		
Comp	oonents:			
<b>Estra</b> Biode	<b>diol:</b> gradability	:	Result: rapidly de Biodegradation: Exposure time: 24	84 %
Magn	esium stearate:			
-	gradability	:	Result: Not biode Remarks: Based	gradable on data from similar materials
Bioac	cumulative potential			
<u>Comp</u>	oonents:			
17β-h	ydroxyestra-4,9,11-tr	ien-3-	one 17-acetate:	
	on coefficient: n- ol/water	:	log Pow: 3.77	
	on coefficient: n-	:	log Pow: 4.01	
	ol/water			
wagn	esium stearate:			



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octan	ion coefficient: n- ol/water	: log Po	w: > 4
	lity in soil		
<u>Com</u>	oonents:		
	diol: oution among environ- al compartments	: log Ko	c: 3.81
	r <b>adverse effects</b> ata available		
3. DISPO	SAL CONSIDERATION	IS	
Dispo	osal methods		
Waste	e from residues	Dispos	dispose of waste into sewer. e of in accordance with local regulations.
Conta	aminated packaging		containers should be taken to an approved waste har
4. TRAN	SPORT INFORMATION	If not o	ite for recycling or disposal. therwise specified: Dispose of as unused product.
4. TRANS Interr UNR1	national Regulations	If not o	therwise specified: Dispose of as unused product.
Interr UNR	national Regulations	If not o UN 30 ENVIR N.O.S. (Estra	therwise specified: Dispose of as unused product. 77 ONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
Interr UNR UN nu Prope Class	national Regulations IDG umber er shipping name	If not o UN 30 ENVIR N.O.S. (Estra : 9	therwise specified: Dispose of as unused product. 77 ONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
Interr UNR UN nu Prope Class Packi	national Regulations IDG umber er shipping name ng group	If not o UN 30 ENVIR N.O.S. (Estra : 9 : III	therwise specified: Dispose of as unused product. 77 ONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
Interr UNR UN nu Prope Class Packi Label	national Regulations IDG umber er shipping name ng group	If not o UN 30 ENVIR N.O.S. (Estra : 9	therwise specified: Dispose of as unused product. 77 ONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
Interr UNR UN nu Prope Class Packi Label Enviro IATA	national Regulations TDG umber er shipping name ng group s onmentally hazardous -DGR	If not o UN 30 ENVIR N.O.S. (Estra 9 III 9 UI 9 UI 9 UI 9 UI 9 UI 9 UI 9	therwise specified: Dispose of as unused product. 77 ONMENTALLY HAZARDOUS SUBSTANCE, SOLID diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)
Interr UNR UN nu Prope Class Packi Label Enviro IATA UN/IE Prope	national Regulations TDG umber er shipping name ng group s onmentally hazardous -DGR O No. er shipping name	If not o If not o UN 30 ENVIR N.O.S. (Estra 9 III 9 UN 30 Enviro (Estra	therwise specified: Dispose of as unused product. 77 ONMENTALLY HAZARDOUS SUBSTANCE, SOLID, diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)
Interr UNR UN nu Prope Class Packi Label Enviro IATA UN/IE Prope	national Regulations FDG umber er shipping name ng group s onmentally hazardous -DGR O No. er shipping name	If not o UN 30' ENVIR N.O.S. (Estra 9 III 9 UN 30' Envirou (Estra 3 9 2 UN 30' 2 5 9 3 4 5 9 5 5 5 5 6 5 6 5 6 5 6 5 6 5 6 5 6 6 7 7 8 8 7 8 7 8 7 8 7 8 8 7 8 8 7 8 7 8 8 7 8 8 7 8 7 8 8 7 8 8 8 7 8 8 8 7 8 8 8 8 8 8 8 8 8 8 8 8 8	therwise specified: Dispose of as unused product. 77 ONMENTALLY HAZARDOUS SUBSTANCE, SOLID, diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate) 77 mmentally hazardous substance, solid, n.o.s.
4. TRANS	national Regulations FDG umber er shipping name ng group s onmentally hazardous -DGR 0 No. er shipping name	If not o If not o UN 30 ENVIR N.O.S. (Estra 9 III 9 UN 30 Enviro (Estra 9 UN 30 Enviro (Estra 9 UN 30 Enviro (Estra	therwise specified: Dispose of as unused product. 77 77 77 76 diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate) 77 nmentally hazardous substance, solid, n.o.s. diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)
4. TRANS	Anational Regulations FDG umber er shipping name ng group s onmentally hazardous -DGR 0 No. er shipping name ng group s ng group s ng group s ng group s ng group s ng group s ng group s	If not o If not o UN 30 ENVIR N.O.S. (Estra 9 III 9 UN 30 Enviro (Estra 9 UN 30 Enviro (Estra 9 UN 30 Enviro (Estra	therwise specified: Dispose of as unused product. 77 ONMENTALLY HAZARDOUS SUBSTANCE, SOLID, diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate) 77 mmentally hazardous substance, solid, n.o.s.
Interr UNR UN nu Prope Class Packi Label Enviro IATA UN/IE Prope Class Packi Label Prope	Anational Regulations TDG umber er shipping name Ing group s onmentally hazardous -DGR D No. er shipping name Ing group s ng group s ng instruction (cargo ft) ng instruction (passen- rcraft)	If not o UN 30 ENVIR N.O.S. (Estra 9 III 9 UN 30 Environ (Estra 9 III Miscell 956 956	therwise specified: Dispose of as unused product. 77 77 77 76 diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate) 77 nmentally hazardous substance, solid, n.o.s. diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)
Interr UNR UN nu Prope Class Packi Label Enviro IATA UN/IE Prope Class Packi Label Prope Class Packi Label Prope	Anational Regulations TDG umber er shipping name ang group s commentally hazardous -DGR 0 No. er shipping name ang group s ng instruction (cargo ft) ng instruction (passen- rcraft) commentally hazardous	If not o If not o UN 30 ENVIR N.O.S. (Estra 9 III 9 UN 30 Environ (Estra 9 III Miscell 956	therwise specified: Dispose of as unused product. 77 77 77 76 diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate) 77 nmentally hazardous substance, solid, n.o.s. diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)
Interr UNR UN nu Prope Class Packi Label Enviro IATA UN/IE Prope Class Packi Label Prope Class Packi Label Prope Class Packi Label Prope	Anational Regulations TDG umber er shipping name Ing group s onmentally hazardous -DGR D No. er shipping name Ing group s ng group s ng instruction (cargo ft) ng instruction (passen- rcraft)	If not o UN 30 ENVIR N.O.S. (Estra 9 III 9 UN 30 Environ (Estra 9 III Miscell 956 956	therwise specified: Dispose of as unused product. 77 ONMENTALLY HAZARDOUS SUBSTANCE, SOLID, diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate) 77 nmentally hazardous substance, solid, n.o.s. diol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate) aneous



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Labels EmS ( Marine <b>Trans</b>	Code e pollutant	: 9 : III : 9 : F-A, S-F : yes ng to Annex II of MAF	hydroxyestra-4,9,11-trien-3-one 17-acetate) RPOL 73/78 and the IBC Code

#### 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.

#### **15. REGULATORY INFORMATION**

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

# Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

#### Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

# Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

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

AICS	: not determine	ed
DSL	: not determin	ed



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	IECSC		:	not determined	
16.	OTHER	INFORMATION			
	Revisio	n Date	:	2023/11/16	
	Furthe	r information			
	Sources of key data used to compile the Safety Data Sheet		:		data, data from raw material SDSs, OECD arch results and European Chemicals Agen- ropa.eu/
	Date format		:	yyyy/mm/dd	
	Full text of other abbreviati		ons		
	ACGIH ID OEL		:		eshold Limit Values (TLV) ational Exposure Limits
	ACGIH / TWA ID OEL / NAB		:	8-hour, time-weig Long term exposu	-

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



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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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