

Estradiol Gel Formulation

Vers 3.0	ion	Revision Date: 06.04.2024		5 Number: 08789-00007	Date of last issue: 30.09.2023 Date of first issue: 08.02.2022				
Sect	Section 1: Identification								
	Produc	t identifier	:	Estradiol Gel For	mulation				
	Recom	mended use of the ch	iemi	cal and restrictio	ons on use				
		nended use	:	Pharmaceutical					
	Restricti	ons on use	:	Not applicable					
	Manufa	cturer or supplier's d	etai	ls					
	Compar	ıy	:	Organon & Co.					
	Address	;	:	30 Hudson Stree Jersey City, New	t, 33nd floor Jersey, U.S.A 07302				
	Telepho	ne		+1-551-430-6000)				
			•						
	Emerge	ncy telephone number	:	+1-215-631-6999)				
	E-mail a	ddress	:	EHSSTEWARD@	⊉organon.com				

Section 2: Hazard identification

Classification of the substance or mixture

Flammable liquids	:	Category 2
Serious eye damage/eye irri- tation	:	Category 2
Carcinogenicity	:	Category 1A
Reproductive toxicity	:	Category 1A
Specific target organ toxicity - repeated exposure	:	Category 1 (Liver, Bone, Blood, Endocrine system)
Long-term (chronic) aquatic hazard	:	Category 1

GHS Label elements, including precautionary statements

Hazard pictograms	
Signal word	: Danger
Hazard statements	: H225 Highly flammable liquid and vapour.



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		H350 May caus H360FD May d H372 Causes c crine system) tl	serious eye irritation. se cancer. amage fertility. May damage the unborn child. Jamage to organs (Liver, Bone, Blood, Endo- nrough prolonged or repeated exposure. c to aquatic life with long lasting effects.
Preca	autionary statements	P202 Do not ha	
		and other igniti P233 Keep cor P241 Use expl ment. P242 Use non-	ay from heat, hot surfaces, sparks, open flame on sources. No smoking. Itainer tightly closed. osion-proof electrical/ ventilating/ lighting equip sparking tools. on to prevent static discharges.
		P260 Do not br P264 Wash ski P270 Do not ea P273 Avoid rele P280 Wear pro	
		ly all contamina P305 + P351 + for several min easy to do. Cor P308 + P313 If attention.	exposed or concerned: Get medical advice/ eye irritation persists: Get medical advice/ at-
		Storage: P403 + P235 S P405 Store loc	tore in a well-ventilated place. Keep cool. ked up.
		Disposal:	of contents/ container to an approved waste

Other hazards which do not result in classification

Vapours may form explosive mixture with air.

Section 3: Composition/information on ingredients

Substance / Mixture

: Mixture



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Components

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	58.5
Estradiol	50-28-2	0.1
# Voluntarily disclosed substance	•	•

Voluntarily-disclosed substance

Section 4: First-aid measures

Description of necessary 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	 In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention. 					
If swallowed	 If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. 					
Most important symptoms	Most important symptoms and effects, both acute and delayed					
Risks	 Causes serious eye irritation. May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. 					
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).					
Indication of any immedia	medical attention and special treatment needed					
Treatment	: Treat symptomatically and supportively.					
ction 5: Eiro-fighting mossu						

Section 5: Fire-fighting measures

Extinguishing media		
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing	:	High volume water jet



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me	Jia			
Spe	cial hazards arising fro	om tl	he substance or m	nixture
			fire. Flash back possi Vapours may fori	d water stream as it may scatter and spread ble over considerable distance. m explosive mixtures with air. bustion products may be a hazard to health.
Haz	ardous combustion prod	- :	Carbon oxides	

Special protective actions for fire-fighters

Special protective equipment for firefighters Specific extinguishing meth- ods		In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
---	--	---

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).		
Environmental precautions			
Environmental precautions	 Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. 		

Methods and materials for containment and cleaning up

Methods for cleaning up	:	Non-sparking tools should be used.
		Soak up with inert absorbent material.
		Suppress (knock down) gases/vapours/mists with a water spray jet.
		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- bent.
		Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items





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		m Se	ine which reguer to the sections 13 and	cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regardin national requirements.			
Section 7	: Handling and storag	le					
Preca	autions for safe hand	ling					
Tech	nical measures			g measures under EXPOSURE RSONAL PROTECTION section.			
Local	/Total ventilation	: If ve Us	sufficient venti ntilation. se explosion-p	roof electrical, ventilating and lighting equip-			
Advice on safe handling : Hygiene measures :		: Do Do Do W Ha pr se No Ke ot Ta ot Ta er : If flu pla W	 ment. Do not get on skin or clothing. Do not breathe vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Non-sparking tools should be used. Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. 				
Cond		Th er ap ind us	ne effective op ngineering con opropriate deg dustrial hygien se of administr	ated clothing before re-use. eration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, he monitoring, medical surveillance and the ative controls.			
	litions for safe storag			-			
	itions for safe storage rials to avoid	St Ke St E St St St	ore locked up eep tightly close eep in a cool, v ore in accorda eep away from o not store with	eed. well-ventilated place. ance with the particular national regulations. a heat and sources of ignition. h the following product types: ostances and mixtures			



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Oxidizing agents Flammable gases Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Poisonous gases Explosives

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Ethanol	64-17-5	PEL (long term)	1,000 ppm 1,880 mg/m3	SG OEL
		STEL	1,000 ppm	ACGIH
Estradiol	50-28-2	TWA	0.05 µg/m3 (OEB 5)	Internal
	Further information: Skin			
		Wipe limit	0.5 µg/100 cm ²	Internal

Appropriate engineering : control measures	Use closed processing systems or containment technologies 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.
	Use explosion-proof electrical, ventilating and lighting equip- ment.
Individual protection measure	s, such as personal protective equipment (PPE)
Eye/face protection :	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 protection :	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-



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Fil	Respiratory protection Filter type Hand protection		Use appropriate contaminated cl If adequate loca sure assessmen ommended guid	o avoid exposed skin surfaces. degowning techniques to remove potentially othing. I exhaust ventilation is not available or expo- nt demonstrates exposures outside the rec- lelines, use respiratory protection. culates and organic vapour type
Ma	Material		Chemical-resista	ant gloves
Remarks		:		e gloving. Take note that the product is flam- ay impact the selection of hand protection.

Section 9: Physical and chemical properties

Appearance	:	gel
Colour	:	opalescent
Odour	:	aromatic
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	:	22 °C
		Method: closed cup
Evaporation rate	:	No data available
Evaporation rate Flammability (solid, gas)	:	No data available Not applicable
Flammability (solid, gas)	:	Not applicable Ignitable (see flash point)
Flammability (solid, gas) Flammability (liquids) Upper explosion limit / Upper	:	Not applicable Ignitable (see flash point) No data available
Flammability (solid, gas) Flammability (liquids) Upper explosion limit / Upper flammability limit Lower explosion limit / Lower	:	Not applicable Ignitable (see flash point) No data available
Flammability (solid, gas) Flammability (liquids) Upper explosion limit / Upper flammability limit Lower explosion limit / Lower flammability limit	:	Not applicable Ignitable (see flash point) No data available No data available



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Den	sity	:	No data available	e
	Solubility(ies) Water solubility		No data availabl	e
	Partition coefficient: n- octanol/water Auto-ignition temperature		Not applicable	
			No data available	e
Dec	Decomposition temperature		No data available	e
	Viscosity Viscosity, kinematic Explosive properties		No data available	e
Expl			Not explosive	
Oxic	lizing properties	:	The substance of	r mixture is not classified as oxidizing.
Mole	ecular weight	:	No data available	9
	icle characteristics icle size	:	Not applicable	

Section 10: Stability and reactivity

Reactivity Chemical stability Possibility of hazardous reac- tions	 Not classified as a reactivity hazard. Stable under normal conditions. Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents. 	
Conditions to avoid Incompatible materials Hazardous decomposition products	 Heat, flames and sparks. Oxidizing agents No hazardous decomposition products are known. 	

Section 11: Toxicological information

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

Acute toxicity

Not classified based on available information.

Components:

Ethanol:

Acute oral toxicity

: LD50 (Rat): > 5,000 mg/kg



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			Method: OECD Te	est Guideline 401
Acute	Acute inhalation toxicity		LC50 (Rat): 124.7 Exposure time: 4 Test atmosphere:	h
Estra	adiol:			
Acute	e oral toxicity	:	LD50 (Rat): > 2,00	00 mg/kg
	Acute toxicity (other routes of administration)		LD50 (Rat): > 300 Application Route	
II Skin	corrosion/irritation			
Not c	lassified based on availa	ble	information.	
Com	ponents:			
Etha				
Spec Meth		:	Rabbit OECD Test Guide	line 404
Resu		÷	No skin irritation	
Caus	ous eye damage/eye irri es serious eye irritation. ponents:	tati	on	
Etha	nol:			
Spec		:	Rabbit	
Resu Meth		:	OECD Test Guide	eversing within 21 days line 405
Estra	adiol:			
Resu	lt	:	No eye irritation	
Resp	piratory or skin sensitis	atic	'n	
Skin	sensitisation			
Not c	lassified based on availa	ble	information.	
•	piratory sensitisation			
	lassified based on availa	ble	information.	
<u>Com</u>	ponents:			
Etha				
Test Expo	Type sure routes	:	Local lymph node Skin contact	assay (LLNA)
Spec	ies	:	Mouse	
Resu	IIT	:	negative	



ersion)	Revision Date: 06.04.2024		S Number: 308789-00007	Date of last issue: 30.09.2023 Date of first issue: 08.02.2022		
Speci	sure routes es ssment	: :	Skin contact Guinea pig Does not cause negative	skin sensitisation.		
	cell mutagenicity lassified based on ava	ailable i	nformation.			
<u>Com</u>	oonents:					
Ethar						
Geno	toxicity in vitro	:	Test Type: In vit Result: negative	ro mammalian cell gene mutation test		
			Test Type: Bactor Result: negative	erial reverse mutation assay (AMES)		
Geno	toxicity in vivo	:	Test Type: Rodent dominant lethal test (germ cell) (in vivo Species: Mouse Application Route: Ingestion Result: equivocal			
Estra	diol:					
Genotoxicity in vitro		:		damage and repair, unscheduled DNA syn alian cells (in vitro) ammalian cells		
			Test Type: Chro Test system: ma Result: positive	mosome aberration test in vitro ammalian cells		
			Test Type: Chro Test system: ma Result: positive	mosomal aberration ammalian cells		
Geno	toxicity in vivo	:	Test Type: Chro Species: Rat Cell type: Bone Result: negative			
			Test Type: Chro Species: Mouse Cell type: Bone Result: negative	marrow		

Carcinogenicity

May cause cancer.



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Com	ponents:			
Estra	diol:			
Expo LOAE Resu Targe	cation Route sure time EL It et Organs		Mouse Ingestion 24 Months 100 µg/kg positive female reproducti	ive organs
Expo LOAE Resu	cation Route sure time EL		Rat Subcutaneous 13 weeks 20 mg/kg body we positive Endocrine system	
Carci ment	nogenicity - Assess-	:	Positive evidence	from human epidemiological studies
-	oductive toxicity damage fertility. May da	amag	e the unborn child.	
Com	ponents:			
Ethai	nol:			
Effect	ts on fertility	:	Test Type: Two-g Species: Mouse Application Route Result: negative	eneration reproduction toxicity study e: Ingestion
Estra	diol:			
	ts on fertility	:	Species: Rat Application Route	0.5 mg/kg body weight
			Species: Rat Duration of Single	e Treatment: 90 d 0.69 mg/kg body weight n fertility
			Test Type: Two-g Species: Mouse Application Route Fertility: LOAEL: Result: Effects or	e: Oral 0.1 mg/kg body weight
Effect ment	ts on foetal develop-	:	Test Type: Embry Species: Mouse,	/o-foetal development female



ersion)	Revision Date: 06.04.2024	SDS Number: 10608789-00007	Date of last issue: 30.09.2023 Date of first issue: 08.02.2022
		Teratogenicity: I Symptoms: Mall	te: Subcutaneous _OAEL: 4 mg/kg body weight formations were observed. Teratogenic effects
		Species: Rat Application Rou Teratogenicity: I Symptoms: Red	egeneration reproduction toxicity study te: Subcutaneous _OAEL: 2.5 µg/kg body weight uced body weight Embryotoxic effects and adverse effects on
		the offspring we	re detected.
		Species: Rat Application Rou Developmental Symptoms: Earl number of viable	ryo-foetal development te: Subcutaneous Toxicity: LOAEL: 0.2 mg/kg body weight y Resorptions / resorption rate, Reduced e fetuses, Reduced body weight
			oxic effects and adverse effects on the off- ected only at high maternally toxic doses
Repro	oductive toxicity - As- nent	spring were dete	
sessn STOT		spring were dete	ected only at high maternally toxic doses
sessn STOT Not cl STOT	nent - single exposure assified based on ava - repeated exposur es damage to organs	spring were dete : May damage fer ailable information.	ected only at high maternally toxic doses rtility. May damage the unborn child.
STOT Not cl STOT Cause expos	nent - single exposure assified based on ava - repeated exposur es damage to organs	spring were dete : May damage fer ailable information.	ected only at high maternally toxic doses
STOT Not cl STOT Cause expos	nent - single exposure assified based on ava - repeated exposur es damage to organs sure. ponents:	spring were dete : May damage fer ailable information.	ected only at high maternally toxic doses rtility. May damage the unborn child.
STOT Not cl STOT Cause expose <u>Comp</u> Estra	nent - single exposure assified based on ava - repeated exposur es damage to organs sure. ponents:	spring were dete : May damage fer ailable information. re (Liver, Bone, Blood, En : Liver, Bone, Blo	ected only at high maternally toxic doses rtility. May damage the unborn child.
STOT Not cl STOT Cause expose <u>Comp</u> Estra Targe Asses	nent - single exposure assified based on ava- - repeated exposur es damage to organs sure. 	spring were dete : May damage fer ailable information. re (Liver, Bone, Blood, En : Liver, Bone, Blood, En : Causes damage	ected only at high maternally toxic doses rtility. May damage the unborn child. docrine system) through prolonged or repeate od, Endocrine system
SESSIN STOT Not cl STOT Cause expose Comp Estra Targe Asses Repe	nent - single exposure assified based on ava- - repeated exposur es damage to organs sure. 	spring were dete : May damage fer ailable information. re (Liver, Bone, Blood, En : Liver, Bone, Blood, En : Causes damage	ected only at high maternally toxic doses rtility. May damage the unborn child. docrine system) through prolonged or repeate od, Endocrine system
SESSIN STOT Not cl STOT Cause expose Comp Estra Targe Asses Repe	nent - single exposure assified based on ava- - repeated exposure es damage to organs sure. - conents: diol: - diol: - diol: - ated dose toxicity - bonents:	spring were dete : May damage fer ailable information. re (Liver, Bone, Blood, En : Liver, Bone, Blood, En : Causes damage	ected only at high maternally toxic doses rtility. May damage the unborn child. docrine system) through prolonged or repeate od, Endocrine system
SESSIN STOT Not cl STOT Cause expose Comp Estra Targe Asses Repea Comp Ethar Speci NOAE	nent - single exposure assified based on ava - repeated exposure es damage to organs sure. 	spring were dete : May damage fer ailable information. re (Liver, Bone, Blood, En : Liver, Bone, Blood, En : Causes damage exposure. : Rat : 1,280 mg/kg	ected only at high maternally toxic doses rtility. May damage the unborn child. docrine system) through prolonged or repeate od, Endocrine system
Sesson STOT Not cl STOT Cause expose <u>Comp</u> Estra Targe Asses Repea <u>Comp</u> Ethar Speci NOAE LOAE Applic	nent - single exposure assified based on ava - repeated exposure es damage to organs sure. 	spring were dete : May damage fer ailable information. re (Liver, Bone, Blood, En : Liver, Bone, Blood, En : Causes damage exposure.	ected only at high maternally toxic doses rtility. May damage the unborn child. docrine system) through prolonged or repeate od, Endocrine system
Sesson STOT Not cl STOT Cause expose <u>Comp</u> Estra Targe Asses Repea <u>Comp</u> Ethar Speci NOAE LOAE Applic	nent - single exposure assified based on ava - repeated exposure es damage to organs sure. - conents: diol: - diol: - diolitattatatatatatatatatatatatatatatatatat	spring were dete : May damage fer ailable information. re (Liver, Bone, Blood, En : Liver, Bone, Blood, En : Causes damage exposure. : Rat : 1,280 mg/kg : 3,156 mg/kg : Ingestion	ected only at high maternally toxic doses rtility. May damage the unborn child. docrine system) through prolonged or repeate od, Endocrine system



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LOAEL	: >= 0.17 mg/kg	
Application Route	: Ingestion	
Exposure time	: 90 d	
Application Route Exposure time Target Organs	: Mammary gland, Ova Endocrine system, Bl	ary, Uterus (including cervix), Liver, Bone, ood, Testis

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Estradiol:

Inhalation Skin contact Ingestion	 Symptoms: tingling, Nose bleeding Symptoms: Skin irritation, Redness, pruritis Symptoms: Headache, Gastrointestinal disturbance, Dizziness, Vomiting, Diarrhoea, water retention, liver function change, changes in libido, breast tenderness, menstrual irregularities
II	ularities

Section 12: Ecological information

Toxicity

Components:

Ethanol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 72 h
		EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l Exposure time: 72 h
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)		NOEC (Daphnia magna (Water flea)): 9.6 mg/l Exposure time: 9 d
Toxicity to microorganisms	:	EC50 (Pseudomonas putida): 6,500 mg/l Exposure time: 16 h
Estradiol:		
Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 3.9 mg/l Exposure time: 96 h
Toxicity to daphnia and other	:	EC50 (Daphnia magna (Water flea)): 2.7 mg/l



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aquati	c invertebrates		Exposure time:	48 h
Toxicit plants	ty to algae/aquatic	:	mg/l Exposure time:	kirchneriella subcapitata (green algae)): 1.7 72 h Test Guideline 201
			mg/l Exposure time:	rchneriella subcapitata (green algae)): > 1. 72 h Test Guideline 201
Toxicit icity)	ty to fish (Chronic tox-	:	Exposure time:	latipes (Japanese medaka)): 0.000003 mg/ 160 d Test Guideline 210
	c invertebrates (Chron-	:	NOEC (Daphnia Exposure time: 2	magna (Water flea)): 0.2 mg/l 21 d
	tor (Chronic aquatic	:	1,000	
	y) ty to microorganisms	:	EC50: > 100 mg Exposure time: 3 Test Type: Resp Method: OECD	3 h
			NOEC: 100 mg/ Exposure time: 3 Test Type: Resp Method: OECD	3 h
II Persis	stence and degradabili	ty		
<u>Comp</u>	oonents:	-		
Ethan				
Biode	gradability	:	Result: Readily Biodegradation: Exposure time: 2	84 %
Estrac	diol:			
Biode	gradability	:	Result: rapidly d Biodegradation: Exposure time: 2	84 %
Bioac	cumulative potential			
<u>Comp</u>	oonents:			
Ethan	ol: on coefficient: n-		log Pow: -0.35	



octanol/wa	ater			
Estradiol	:			
Partition c	oefficient: n- ater	:	log Pow: 4.01	
Mobility i	n soil			
Compone	ents:			
Estradiol	:			
Distributio mental co	n among environ- mpartments	:	log Koc: 3.81	
Other adv	verse effects			
No data a	vailable			

Disposal methods		
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 han- dling site for recycling or disposal.
		Empty containers retain residue and can be dangerous.
		Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources
		of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG		
UN number	:	UN 1170
UN proper shipping name	:	ETHANOL SOLUTION
Transport hazard class(es)	:	3
Packing group	:	II
Labels	:	3
Environmental hazards	:	yes
IATA-DGR		
UN/ID No.	:	UN 1170
UN proper shipping name	:	Ethanol solution
Transport hazard class(es)	:	3
Packing group	:	II
Labels	:	Flammable Liquids
Packing instruction (cargo	:	364
aircraft)		
Packing instruction (passen-	:	353
ger aircraft)		

IMDG-Code



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UN number	:	UN 1170
Proper shipping name	:	ETHANOL SOLUTION
		(Estradiol)
Transport hazard class(es)	:	3
Packing group	:	II
Labels	:	3
EmS Code	:	F-E, S-D
Marine pollutant	:	ves

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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.

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.
Environmental Protection and Management Act and Environmental Protection and Management (Hazard-ous Substances) Regulations
Fire Safety (Petroleum and Flammable Materials) : Ethanol
The components of this product are reported in the following inventories:

The compensitie of the pro-		
AICS	•	not determined
DSL	:	not determined
IECSC	:	not determined

Section 16: Other information

Revision Date	:	06.04.2024
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/

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



Version	Revision Date: 06.04.2024	SDS Number:	Date of last issue: 30.09.2023
3.0		10608789-00007	Date of first issue: 08.02.2022

Date format	•	dd.mm.yyyy		
Full text of other abbreviations				
ACGIH SG OEL	:	USA. ACGIH Threshold Limit Values (TLV) Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.		
ACGIH / STEL SG OEL / PEL (long term)	:	Short-term exposure limit Permissible Exposure Level (PEL) Long Term		

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

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.