

SAFETY DATA SHEET



Estradiol Formulation



Version 5.0 Revision Date: 2023/09/30 SDS Number: 2678764-00016 Date of last issue: 2023/04/04
Date of first issue: 2018/04/12

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Estradiol Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia

Telephone : +1-551-430-6000

Emergency telephone number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 3

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

Hazard pictograms :



Signal word : Danger

Hazard statements : H226 Flammable liquid and vapour.
H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs (Liver, Bone, Blood, Endo-

Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

crine system) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

:

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P260 Do not breathe vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	>= 40 -<= 45
Estradiol	50-28-2	0.06

Voluntarily-disclosed substance

4. FIRST AID MEASURES

Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

- 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 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).
- Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- 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 : 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 containment 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 absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe vapours.
Do not swallow.
Avoid contact with 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.

SAFETY DATA SHEET



Estradiol Formulation



Version 5.0 Revision Date: 2023/09/30 SDS Number: 2678764-00016 Date of last issue: 2023/04/04
Date of first issue: 2018/04/12

- Conditions for safe storage : 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.
: Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
- Materials to avoid : Keep away from heat and sources of ignition.
: Do not store with the following product types:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Flammable gases
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Poisonous gases
Explosives

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	PSD	1,000 ppm	ID OEL
			Further information: Confirmed animal carcinogen.	
		STEL	1,000 ppm	ACGIH
Estradiol	50-28-2	TWA	0.05 µg/m ³ (OEB 5)	Internal
			Further information: Skin	
		Wipe limit	0.5 µg/100 cm ²	Internal

- Engineering measures** : Minimize workplace exposure concentrations.
If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Organic vapour type
- Hand protection
- Material : Chemical-resistant gloves

SAFETY DATA SHEET



Estradiol Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

- Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Take note that the product is flammable, which may impact the selection of hand protection. Wash hands before breaks and at the end of workday.
- Eye protection : Wear the following personal protective equipment:
Safety glasses
- Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Wear the following personal protective equipment:
If assessment demonstrates that there is a risk of explosive atmospheres or flash fires, use flame retardant antistatic protective clothing.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
- Hygiene measures : 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.
Wash contaminated clothing before re-use.
-

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : gel
- Colour : clear, colourless
- Odour : No data available
- Odour Threshold : No data available
- pH : 6.6 - 6.8
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : 27 - 30 °C
Method: closed cup
- Evaporation rate : No data available
- Flammability (solid, gas) : No data available
- Flammability (liquids) : Ignitable (see flash point)

SAFETY DATA SHEET



Estradiol Formulation



Version 5.0 Revision Date: 2023/09/30 SDS Number: 2678764-00016 Date of last issue: 2023/04/04
Date of first issue: 2018/04/12

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 : 60000 - 85000 mm²/s

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : Not applicable

Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

Respiratory sensitisation

Not classified based on available information.

Components:**Ethanol:**

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse
Result	: negative

Estradiol:

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

Germ cell mutagenicity

Not classified based on available information.

Components:**Ethanol:**

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test
	Result: negative
Genotoxicity in vivo	: Test Type: Bacterial reverse mutation assay (AMES)
	Result: negative
Genotoxicity in vivo	: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
	Species: Mouse
	Application Route: Ingestion
	Result: equivocal

Estradiol:

Genotoxicity in vitro	: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
	Test system: mammalian cells
	Result: positive
Genotoxicity in vitro	: Test Type: Chromosome aberration test in vitro
	Test system: mammalian cells
	Result: positive
Genotoxicity in vitro	: Test Type: Chromosomal aberration
	Test system: mammalian cells
	Result: positive
Genotoxicity in vivo	: Test Type: Chromosomal aberration
	Species: Rat
	Cell type: Bone marrow

Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

Result: negative

Test Type: Chromosomal aberration

Species: Mouse

Cell type: Bone marrow

Result: negative

Carcinogenicity

May cause cancer.

Components:**Estradiol:**

Species	: Mouse
Application Route	: Ingestion
Exposure time	: 24 Months
LOAEL	: 100 µg/kg
Result	: positive
Target Organs	: female reproductive organs

Species	: Rat
Application Route	: Subcutaneous
Exposure time	: 13 weeks
LOAEL	: 20 mg/kg body weight
Result	: positive
Target Organs	: Endocrine system

Carcinogenicity - Assessment	: Positive evidence from human epidemiological studies
------------------------------	--

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:**Ethanol:**

Effects on fertility	: Test Type: Two-generation reproduction toxicity study
	Species: Mouse
	Application Route: Ingestion
	Result: negative

Estradiol:

Effects on fertility	: Test Type: One-generation reproduction toxicity study
	Species: Rat
	Application Route: Ingestion
	Fertility: LOAEL: 0.5 mg/kg body weight
	Result: Effects on fertility

Test Type: One-generation reproduction toxicity study

Species: Rat

Duration of Single Treatment: 90 d

Fertility: LOAEL: 0.69 mg/kg body weight

Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

		Result: Effects on fertility
		Test Type: Two-generation study Species: Mouse Application Route: Oral Fertility: LOAEL: 0.1 mg/kg body weight Result: Effects on fertility
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Mouse, female Application Route: Subcutaneous Teratogenicity: LOAEL: 4 mg/kg body weight Symptoms: Malformations were observed. Result: positive, Teratogenic effects
		Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Subcutaneous Teratogenicity: LOAEL: 2.5 µg/kg body weight Symptoms: Reduced body weight Result: positive, Embryotoxic effects and adverse effects on the offspring were detected.
		Test Type: Embryo-foetal development Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.2 mg/kg body weight Symptoms: Early Resorptions / resorption rate, Reduced number of viable fetuses, Reduced body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses
Reproductive toxicity - Assessment	:	May damage fertility. May damage the unborn child.

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.

Components:**Estradiol:**

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

Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

Repeated dose toxicity**Components:****Ethanol:**

Species	:	Rat
NOAEL	:	1,280 mg/kg
LOAEL	:	3,156 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Estradiol:

Species	:	Rat
LOAEL	:	>= 0.17 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 d
Target Organs	:	Mammary gland, Ovary, Uterus (including cervix), Liver, Bone, Endocrine system, Blood, Testis

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Estradiol:**

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

12. ECOLOGICAL INFORMATION**Ecotoxicity****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

SAFETY DATA SHEET



Estradiol Formulation



Version 5.0 Revision Date: 2023/09/30 SDS Number: 2678764-00016 Date of last issue: 2023/04/04
Date of first issue: 2018/04/12

Toxicity to daphnia and other aquatic invertebrates (Chronic 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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.7 mg/l
Exposure time: 48 h
Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 1.7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
EC50 (Pseudokirchneriella subcapitata (green algae)): > 1.7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): 0.000003 mg/l
Exposure time: 160 d
Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.2 mg/l
Exposure time: 21 d
M-Factor (Chronic aquatic toxicity) : 1,000
Toxicity to microorganisms : EC50: > 100 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
NOEC: 100 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Ethanol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

II

Estradiol:

Biodegradability	:	Result: rapidly degradable
		Biodegradation: 84 %
		Exposure time: 24 hrs

Bioaccumulative potential**Components:****Ethanol:**

Partition coefficient: n-octanol/water	:	log Pow: -0.35
--	---	----------------

Estradiol:

Partition coefficient: n-octanol/water	:	log Pow: 4.01
--	---	---------------

Mobility in soil**Components:****Estradiol:**

Distribution among environmental compartments	:	log Koc: 3.81
---	---	---------------

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**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 handling 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.

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number	:	UN 1170
Proper shipping name	:	ETHANOL SOLUTION
Class	:	3
Packing group	:	III
Labels	:	3

Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 1170
 Proper shipping name : Ethanol solution
 Class : 3
 Packing group : III
 Labels : Flammable Liquids
 Packing instruction (cargo aircraft) : 366
 Packing instruction (passenger aircraft) : 355

IMDG-Code

UN number : UN 1170
 Proper shipping name : ETHANOL SOLUTION
 (Estradiol)
 Class : 3
 Packing group : III
 Labels : 3
 EmS Code : F-E, S-D
 Marine pollutant : yes

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

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.

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 : Ethanol

Prohibited substances : Not applicable

Restricted substances : Not applicable

Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

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 control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : 2,2',2''-Nitrilotriethanol

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 : 2023/09/30

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.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ID OEL	:	Indonesia. Occupational Exposure Limits

ACGIH / STEL	:	Short-term exposure limit
ID OEL / PSD	:	Short term exposure limit

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 Con-

SAFETY DATA SHEET



Estradiol Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.0	2023/09/30	2678764-00016	Date of first issue: 2018/04/12

centration 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.

ID / EN