

SAFETY DATA SHEET



Estradiol Gel Formulation



Version 5.0 Revision Date: 2024/04/06 SDS Number: 10608785-00007 Date of last issue: 2023/09/30
Date of first issue: 2022/02/08

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Estradiol Gel Formulation

Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : +1-551-430-6000

E-mail address : EHSSTEWARD@organon.com

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

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Flammable liquids : Category 2

Serious eye damage/eye irritation : Category 2A

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 : H225 Highly flammable liquid and vapour.

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H319 Causes serious eye irritation.
H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs (Liver, Bone, Blood, Endocrine 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, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
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.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: 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

Important symptoms and outlines of the emergency assumed : Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Ethanol#	64-17-5	58.5	2-202
Propylene glycol	57-55-6	12.5	2-234
Polyacrylic acid	9003-01-4	1.5	6-898
2,2',2''-Nitrilotriethanol	102-71-6	0.28	2-308, 2-353
Estradiol	50-28-2	0.1	

Voluntarily-disclosed substance

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : 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 and effects, both acute and delayed : 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).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

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- 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.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.
Ventilate the area.
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.

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7. HANDLING AND STORAGE
Handling

- 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.
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.
- Avoidance of contact : Oxidizing agents
- 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.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage

- Conditions for safe storage : 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.
Keep away from heat and sources of ignition.
- Materials to avoid : Do not store with the following product types:
Oxidizing solids
Oxidizing liquids
- Packaging material : Unsuitable material: None known.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
Ethanol	64-17-5	STEL	1,000 ppm	ACGIH
2,2',2''-Nitrilotriethanol	102-71-6	TWA	5 mg/m ³	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 : Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent 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 technology designed to prevent leakage of compounds into the workplace. 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 : Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

Eye 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 and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the

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task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	gel
Colour	:	opalescent
Odour	:	aromatic
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Ignitable (see flash point)
Lower explosion limit and upper explosion limit / flammability limit		
Upper explosion limit / Upper per flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	22 °C
		Method: closed cup
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available

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Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics
Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Highly 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 exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Ethanol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124.7 mg/l
Exposure time: 4 h
Test atmosphere: vapour

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II

Propylene glycol:

Acute oral toxicity	:	LD50 (Rat): 22,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 44.9 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

Polyacrylic acid:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: Based on data from similar materials
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2,2',2''-Nitrilotriethanol:

Acute oral toxicity	:	LD50 (Rat): 6,400 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg

Estradiol:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): > 300 mg/kg Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

Components:**Ethanol:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Propylene glycol:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Polyacrylic acid:

Species	:	Rabbit
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

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2,2',2''-Nitrilotriethanol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**Ethanol:**

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

Propylene glycol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Polyacrylic acid:

Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

2,2',2''-Nitrilotriethanol:

Species : Rabbit
Result : No eye irritation

Estradiol:

Result : No eye irritation

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

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

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Propylene glycol:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

2,2',2''-Nitrilotriethanol:

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

Propylene glycol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES)
	Result: negative
	: Test Type: Chromosome aberration test in vitro
Genotoxicity in vivo	Method: OECD Test Guideline 473
	Result: negative
	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
	Species: Mouse
Genotoxicity in vivo	Application Route: Intraperitoneal injection
	Result: negative

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2,2',2''-Nitrilotriethanol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Estradiol:

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

Test Type: Chromosome aberration test in vitro
Test system: mammalian cells
Result: positive

Test Type: Chromosomal aberration
Test system: mammalian cells
Result: positive

Genotoxicity in vivo : Test Type: Chromosomal aberration
Species: Rat
Cell type: Bone marrow
Result: negative

Test Type: Chromosomal aberration
Species: Mouse
Cell type: Bone marrow
Result: negative

Carcinogenicity

May cause cancer.

Components:**Propylene glycol:**

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

2,2',2''-Nitrilotriethanol:

Species : Rat
Application Route : Skin contact
Exposure time : 103 weeks
Result : negative

Estradiol:

Species : Mouse
Application Route : Ingestion
Exposure time : 24 Months
LOAEL : 100 µg/kg

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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

Propylene glycol:

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

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

2,2',2"-Nitrilotriethanol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

Effects on foetal development : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 421
Result: negative

Estradiol:

Effects on fertility : Test Type: One-generation reproduction toxicity study

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<p>Effects on foetal development</p>	<p>Species: Rat Application Route: Ingestion Fertility: LOAEL: 0.5 mg/kg body weight Result: Effects on fertility</p> <p>Test Type: One-generation reproduction toxicity study Species: Rat Duration of Single Treatment: 90 d Fertility: LOAEL: 0.69 mg/kg body weight Result: Effects on fertility</p> <p>Test Type: Two-generation study Species: Mouse Application Route: Oral Fertility: LOAEL: 0.1 mg/kg body weight Result: Effects on fertility</p> <p>: 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</p> <p>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.</p> <p>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</p>
<p>Reproductive toxicity - Assessment</p>	<p>: May damage fertility. May damage the unborn child.</p>

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.

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Components:**2,2',2''-Nitrilotriethanol:**

Assessment	:	No significant health effects observed in animals at concentrations of 200 mg/kg bw or less. No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.
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Estradiol:

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

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

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

Propylene glycol:

Species	:	Rat, male
NOAEL	:	>= 1,700 mg/kg
Application Route	:	Ingestion
Exposure time	:	2 yr

2,2',2''-Nitrilotriethanol:

Species	:	Rat
NOAEL	:	>= 1,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Species	:	Rat
NOAEL	:	>= 0.5 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	28 Days
Method	:	OECD Test Guideline 412

Species	:	Rat
NOAEL	:	125 mg/kg
Application Route	:	Skin contact
Exposure time	:	90 Days

Estradiol:

Species	:	Rat
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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
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

Propylene glycol:

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
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	Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d
Toxicity to microorganisms	: NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h

Polyacrylic acid:

Toxicity to fish	: LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): > 1 mg/l Exposure time: 32 d Remarks: Based on data from similar materials
Toxicity to microorganisms	: EC50 (activated sludge): > 100 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials

2,2',2''-Nitrilotriethanol:

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): 11,800 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Ceriodaphnia dubia (water flea)): 609.88 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: ErC50 (Desmodesmus subspicatus (green algae)): 512 mg/l Exposure time: 72 h Test substance: Neutralised product
	: EC10 (Desmodesmus subspicatus (green algae)): 26 mg/l Exposure time: 72 h Test substance: Neutralised product
Toxicity to daphnia and other	: NOEC (Daphnia magna (Water flea)): 16 mg/l

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aquatic invertebrates (Chronic toxicity)	Exposure time: 21 d
Toxicity to microorganisms	: IC50: > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

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
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Propylene glycol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F
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Polyacrylic acid:

Biodegradability	:	Result: Not readily biodegradable. Remarks: Based on data from similar materials
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2,2',2''-Nitrilotriethanol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 96 % Exposure time: 19 d
------------------	---	---

Estradiol:

Biodegradability	:	Result: rapidly degradable Biodegradation: 84 % Exposure time: 24 hrs
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Bioaccumulative potential**Components:****Ethanol:**

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

Propylene glycol:

Partition coefficient: n-octanol/water	:	log Pow: -1.07 Method: Regulation (EC) No. 440/2008, Annex, A.8
--	---	--

2,2',2''-Nitrilotriethanol:

Bioaccumulation	:	Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): < 3.9
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Partition coefficient: n-octanol/water	:	log Pow: -1.9
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Estradiol:

Partition coefficient: n-octanol/water	:	log Pow: 4.01
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Mobility in soil**Components:****Estradiol:**

Distribution among environmental compartments	:	log Koc: 3.81
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Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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	:	II
Labels	:	3
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 1170
Proper shipping name	:	Ethanol solution
Class	:	3
Packing group	:	II
Labels	:	Flammable Liquids
Packing instruction (cargo aircraft)	:	364
Packing instruction (passenger aircraft)	:	353

IMDG-Code

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

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code : 127

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Group 4, Type 2 petroleum, Water insoluble liquid, (1000 litre), Hazardous rank III

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Propane-1,2-diol	106
Acrylic acid polymer	234
Triethanolamine	108

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Ethanol	>=50 - <60	-
propane-1,2-diol	>=10 - <20	From April 1st, 2025
Triethanolamine	>0 - <10	-

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Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Ethanol	-
propane-1,2-diol	From April 1st, 2025

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Inflammable Substance

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Class I Designated Chemical Substances

Chemical name	Administration number	Concentration (%)
Polymer of acrylic acid	565	1.5

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Flammable liquids (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Flammable liquid (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Classified as marine pollutant

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Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Specially Controlled Industrial Waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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)

ACGIH / TWA : 8-hour, time-weighted average

ACGIH / STEL : 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-

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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.

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