

**SAFETY DATA SHEET**

According to Regulation 1907/2006/EC and EG Nr. 1272/2008

**17 ALPHA ESTRADIOL**

VERSION: 02 – 10.06.14

**1. Identification of the substance/preparation and of the company/undertaking**

1.1	Commercial product name:	<b>17 Alpha Estradiol</b>
1.2	Synonymous:	No data available
1.3	Use:	Active ingredient
1.4	Product code:	06000574
1.6	Company:	Productos Químicos Naturales S.A. de C.V. Calzada Ojo de Agua s/n 94450 Ixtaczoquitlán, Ver. México Phone 52(272) 74 2 5695, 74 2 5694
1.7	Emergency phone number:	PROQUINA SALUD, SEGURIDAD Y MEDIO AMBIENTE. Phone 52(272) 74 2 5693, 74 2 5668

**2. Hazards identification****GHS-Classification (according to EC 1272/2008):**

Carcinogenicity, Category 2 (H351)  
Reproductive toxicity, Category 1A (H360Fd)  
Effects on or via lactation (H362)

**Classification (67/548/EEC, 1999/45/EC):**

Carcinogenic Category 3  
Toxic to Reproduction Category 1  
Toxic to Reproduction Category 3  
Limited evidence of a carcinogenic effect.  
May impair fertility.  
Possible risk of harm to the unborn child.  
May cause harm to breastfed babies.

**GHS-Labeling (according to EC 1272/2008):**

Danger

**Hazard statements:**

H351 Suspected of causing cancer.  
H360Fd May damage fertility. Suspected of damaging the unborn child.  
H362 May cause harm to breast-fed children.

**Precautionary statements:****Prevention:**

P281 Use personal protective equipment as required.  
P260 Do not breathe dust or mist.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

Other hazards which do not result in classification:

None known.

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**17 ALPHA ESTRADIOL****3. Composition/Information on ingredients.**

This product is a substance within the meaning of Regulation (EC) No. 1907/2006.

**Hazardous components**

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Concentration [Weight percent] ≤ 100

CAS-No.: 57-91-0

CAS name: Estra-1,3,5(10)-triene-3,17-diol, (17.β.)-

EINECS-No.: 200-354-8

**EU - Classification:**

Carcinogenic Category 3 R40



Toxic to Reproduction Category 1 R60



Toxic to Reproduction Category 3 R63, R64

**GHS Classification:**

Carc. 2 H351

Repr. 1A H360Fd

Lact. H362

For the full text of the H+R-phrases mentioned in this Section, see Section 16.

**4. First-aid measures****General advice:**

Take off contaminated clothing and shoes immediately. Call a physician immediately.

**If inhaled:**

Remove to fresh air. If symptoms persist, call a physician.

**In case of skin contact:**

After contact with skin, wash immediately with plenty of soap and water. Do NOT use solvents or thinners.

**In case of eye contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

**If swallowed:** Rinse mouth with water.

**Most important acute symptoms/effects**

**Symptoms:** No information available.

**Risks:** No information available.

**Indication of any immediate medical attention and special treatment needed**

No information available.

**5. Fire-fighting measures****Suitable extinguishing media:**

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**17 ALPHA ESTRADIOL**Water spray jet, Foam, Dry powder, Carbon dioxide (CO<sub>2</sub>).**Unsuitable extinguishing media:**

High volume water jet

**Specific hazards during fire fighting:**Fire may cause evolution of: Carbon dioxide (CO<sub>2</sub>) Carbon Monoxide**Special protective equipment for fire-fighters:**

In the event of fire, wear self-contained breathing apparatus.

**Further information:**

Prevent fire extinguishing water from contaminating surface water or the ground water system.

**6. Accidental release measures****Personal precautions:**

Use personal protective equipment.

**Environmental precautions:**

Do not flush into surface water or sanitary sewer system.

**Methods for cleaning up:**

Use mechanical handling equipment. Avoid dust formation. Return contained product to the manufacturer. Flush with plenty of water.

**Additional advice:**

Avoid dust formation.

**7. Handling and storage****Precautions for safe handling****Handling:**

Avoid contact with skin, eyes and clothing. Only handle product with local exhaust ventilation.

**Conditions for safe storage, including any incompatibilities**

For storage suitable stores with adequate product-reception volume must be used. During handling local official regulations must be observed in order to avert impairment of water by the product.

**Specific end use(s)**

No statements available.

**8. Exposure controls/personal protection**

Components with workplace control parameters (internationally)

Substance	CAS-No.	Basis	Type:	Value	Ceiling Limit Value	Remarks
Estradiol 17 Alpha	57-91-0		OEL *	0.01 mg/m <sup>3</sup>		

\*OEL (BHC) = Occupational Exposure Limit, company threshold limit value (TLV)

**Exposure controls****Personal protective measures:**

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**17 ALPHA ESTRADIOL****Respiratory protection:**

Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)

**Hand protection:****Hand protection:** During the handling of the substance according to the intended use protection gloves from nitrile rubber have been proved.**Eye protection:**

Safety glasses with side-shields

**Skin and body protection:**

Choose body protection according to the amount and concentration of the dangerous substance at the work place. Dust impervious protective suit

**Hygiene measures:**

Wash hands and face before breaks and immediately after handling the product. Use protective skin cream before handling the product. Shower or bathe at the end of working.

**Other protective measures:**

Wear suitable protective equipment.

**9. Physical and chemical properties**

<b>Form:</b>	solid, crystalline
<b>Colour:</b>	off-white
<b>Odour:</b>	odourless
<b>Melting point/range:</b>	220 - 225 °C
<b>Boiling point/boiling range:</b>	No statements available.
<b>Density:</b>	No statements available.
<b>Bulk density:</b>	No statements available.
<b>Vapour pressure:</b>	No statements available.
<b>Viscosity, dynamic:</b>	No statements available.
<b>Viscosity, kinematic:</b>	No statements available.
<b>Flow time:</b>	No statements available.
<b>Surface tension:</b>	No statements available.
<b>Water solubility:</b>	1.3 mg/l at 20 °C
<b>Solubility (ies):</b>	No statements available.
<b>pH:</b>	No statements available.
<b>Partition coefficient (n-octanol/water):</b>	log Pow: 2.71
<b>Flash point:</b>	Not applicable
<b>Inflammability (solid, gaseous):</b>	No statements available.
<b>Explosion limits:</b>	No statements available.
<b>Miscibility with water:</b>	Not applicable



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**10. Stability and Reactivity.**

**Reactivity**

No statements available.

**Reactions with water / air:**

No statements available.

**Ignition temperature:**

No statements available.

**Burning number:**

No statements available.

**Flammability (solid, gas):**

No statements available.

**Chemical stability**

No statements available.

**Thermal decomposition:**

No statements available.

**Dust explosion characteristic number:**

No statements available

**Dust explosion class:**

No statements available

**Explosive properties:**

No statements available.

**Impact Sensitivity:**

no data available

**Hazardous reactions:**

no data available

**Possibility of hazardous reactions**

**deflagration ability:**

No statements available.

**Smoldering combustion:**

No statements available.

**Conditions to avoid**

no data available

**Oxidizing properties:**

No statements available.

**Minimum ignition energy:**

No statements available

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**Incompatible materials**

**Materials to avoid:**

Oxidizing agents

**Hazardous decomposition products**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

**Further information:**

The following applies in general to flammable organic substances and preparations: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

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**11. Toxicological information.**

**Information on toxicological effects**

**Acute oral toxicity:**

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LD<sub>50</sub> mouse: > 4,000 mg/kg

Test substance: data based on the valerate

LD<sub>50</sub> rat: > 4,000 mg/kg

Test substance: data based on the valerate

**Acute inhalation toxicity:**

No statements available.

**Acute dermal toxicity:**

No statements available.

**Acute toxicity (other routes of administration):**

No statements available

**Corrosivity:**

No statements available.

**Skin irritation:**

No statements available.

**Eye irritation:**

No statements available.

**Sensitisation:**

No statements available.

**Phototoxicity:**

No statements available.

**Subacute, subchronic and prolonged toxicity:**

No statements available

**Aspiration toxicity:**

No statements available.

**Genotoxicity in vitro:**

No statements available.

**Genotoxicity in vivo:**

No statements available

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**Carcinogenicity:**

No statements available

**Fertility:**

No statements available

**Human experience:**

No statements available.

**Neurotoxicity:**

No statements available.

**Neurological symptoms:**

No statements available.

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**12. Ecological information.**

**Ecotoxicology Assessment**

No statements available.

**Toxicity**

**Toxicity to fish:**

No statements available.

**Toxicity to daphnia and other aquatic invertebrates:**

No statements available.

**Toxicity to algae:**

No statements available.

**Toxicity to bacteria:**

No statements available.

**Toxicity to fish (Chronic toxicity):**

No statements available.

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**

No statements available.

**Toxicity on soil-dwelling organisms:**

No statements available.

**Toxicity on other terrestrial non-mammal:**

No statements available.

**Persistence and degradability**

**Biodegradability:**

No statements available

**Biochemical Oxygen Demand (BOD):**

No statements available.

**Chemical Oxygen Demand (COD):**

No statements available.

**BSB in proportion to CSB:**

No statements available.

**Dissolved organic carbon (DOC):**

No statements available.

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**BSB in proportion to CSB:**

No statements available.

**Dissolved organic carbon (DOC):**

No statements available.

**Adsorbed organic bound halogens (AOX):**

No statements available.

**Theoretical biological oxygen requirement:**

No statements available.

**BSB in proportion to ThSB:**

No statements available.

**Total organic carbon (TOC):**

No statements available.

**Physico-chemical removability:**

No statements available.

**Stability in water:**

No statements available.

**Additional degradation pathways:**

No statements available.

**Photodegradation:**

No statements available.

**M-Factor:**

No statements available.

**Bioaccumulative potential**

**Bioaccumulation:**

No statements available.

**Partition coefficient (n-octanol/water):**

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log Pow: 2.71

**Environmental distribution:**

No statements available.

**Surface tension:**

No statements available.

**Stability in soil:**

No statements available.

**Results of PBT and vPvB assessment**

No statements available.

**Other adverse effects**

**General advice:**

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No information on ecology is available.

Do not allow to enter surface waters or groundwater.



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**17 ALPHA ESTRADIOL****13. Disposal consideration.****Waste treatment methods**

Transport to suitable incinerator with reduced non-air emission.

Contaminated packaging: Contaminated, empty containers are to be treated in the same way as the contents.

**14. Transport information****ADR/RID** - -**GGVS/GGVE** - -**ADNR** - -**IATA** - -**IMDG** - -**Special precautions for user**

For personal protection see section 8.

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

not applicable

Other information : No dangerous cargo  
Keep separated from foodstuffs**15. Regulatory information.****Safety, health and environmental regulations/legislation specific for the substance or mixture****National legislation****Guidelines and information sheets issued by the Chemical Industry Employers'****Insurance Association:**

M 053 /BGI 660 ("Protective measures when handling hazardous substances at work"), Employers' Liability Insurance Association leaflet (BGI) 5151, Working safely in the pharmaceutical industry (April 2009)., The recommendations given in the leaflet of the "Berufsgenossenschaft der Chemischen Industrie" (Employers' Liability Insurance Association for the German Chemical Industry) entitled "Fruchtschädigungen - Schutz am Arbeitsplatz" (M 039) should be followed.

**Other regulations:**

No statements available.

Observe TRGS 905 (cmr substances).

**Chemical Safety Assessment**

No statements available.



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**16. Other information**

**Full text of R-phrases referred to under sections 2 and 3**

R40 Limited evidence of a carcinogenic effect.

R60 May impair fertility.

R63 Possible risk of harm to the unborn child.

R64 May cause harm to breastfed babies.

**Full text of H-Statements mentioned in chapters 2 and 3**

H351 Suspected of causing cancer.

H360Fd May damage fertility. Suspected of damaging the unborn child.

H362 May cause harm to breast-fed children.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

**Further information**

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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