

ESTRONE

GHS Safety Data Sheet

Version No:2.0

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

ESTRONE

OTHER NAMES

C18-H22-O2, "delta-1, 3, 5-estatrien-3-beta-ol-17-one", "delta-1, 3, 5-estatrien-3-beta-ol-17-one", "delta-1, 3, 5-oestratrien-3-beta-ol-17-one", "delta-1, 3, 5-oestratrien-3-beta-ol-17-one", "1, 3, 5-estatrien-3-ol-17-one", "1, 3, 5-estatrien-3-ol-17-one", "1, 3, 5(10)-estatrien-3-ol-17-one", "1, 3, 5(10)-estatrien-3-ol-17-one", "estra-1, 3, 5(10)-trien-17-one, 3-hydroxy", "estra-1, 3, 5(10)-trien-17-one, 3-hydroxy", "3-hydroxyestra-1, 3, 5(10)-trien-17-one", "3-hydroxyestra-1, 3, 5(10)-trien-17-one", "3-hydroxy-17-keto-estra-1, 3, 5-trien", "3-hydroxy-17-keto-estra-1, 3, 5-trien", "3-hydroxy-17-keto-oestra-1, 3, 5-triene", "3-hydroxy-17-keto-oestra-1, 3, 5-triene", "3-hydroxy-oestra-1, 3, 5(10)-trien-17-one", "3-hydroxy-oestra-1, 3, 5(10)-trien-17-one", ketohydroxy-estratriene

PRODUCT USE

Oestrone is a metabolite of the most potent of the naturally occurring oestrogens, oestradiol. It is secreted by the ovaries in normal adult cycling females and is essential for growth and normal maintenance of the uterine lining, for the development of accessory and secondary female sex characteristics, and for the support of pregnancy. Oestrone is used to treat conditions such as amenorrhoea, breast carcinoma, hypogonadism, menopausal syndrome, postmenopausal osteoporosis, postpartum breast engorgement, prostatic carcinoma and senile vaginitis. It is frequently combined with other hormones and medicinals, such as barbiturates and tranquilizers. The hormone has also been used in hormonal skin preparations for cosmetic use at concentrations typically in the range of less than 0.1%. Synthetic oestrogens are also used in conjugated oestrogens, prescription drugs used to treat symptoms of climacteric, vulvar dystrophies, female hypogonadism and dysfunctional uterine bleeding. They have also been used for treatment following oophorectomy, for chemotherapy of mammary and of prostate carcinoma and for the prevention of post-partum breast enlargement. The conjugated oestrogens have also been used in cosmetics; their use has largely, if not completely, been discontinued, as a result of health concerns. Large quantities of oestrone and oestriol are produced by the placenta during pregnancy. These are also the primary oestrogens produced by the

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adipose tissue in men and in post-menopausal women.

SUPPLIER

Company: S D FINE- CHEM LIMITED

Address:

315- 317, T.V. INDUSTRIAL ESTATE,

248, WORLI,

MUMBAI- 400030.INDIA.

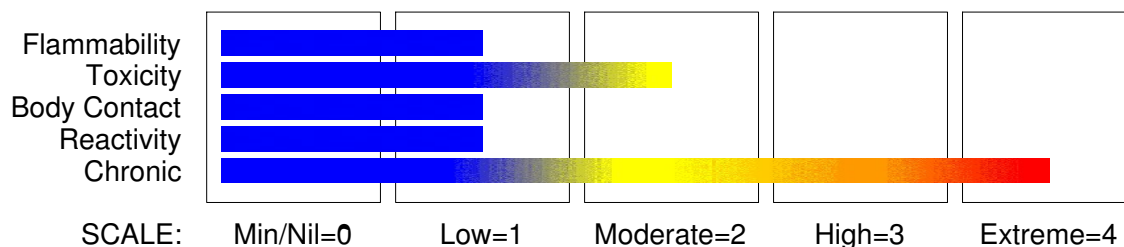
technical@sdfine.com

Telephone: 91- 22- 24959898

Telephone: 91- 22- 24959899

Fax: 91- 22- 24937232

HAZARD RATINGS



Section 2 - HAZARDS IDENTIFICATION

GHS Classification

Carcinogen Category 1A

Reproductive Toxicity Category 1B

Reproductive Toxicity Category 2



EMERGENCY OVERVIEW

HAZARD

DANGER

Determined by using GHS criteria:

H350 H360 H361

May cause CANCER

May damage the unborn child

Suspected of damaging fertility

PRECAUTIONARY STATEMENTS

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Section 2 - HAZARDS IDENTIFICATION

Prevention

Do not handle until all safety precautions have been read and understood.
Use personal protective equipment as required.
Obtain special instructions before use.

Response

If exposed or concerned: Get medical attention advice.

Storage

Store locked up.

Disposal

Dispose of contents and container in accordance with relevant legislation.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
estrone	53-16-7	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

For advice, contact a Poisons Information Centre or a doctor.
Poison Information Centres in each State capital city can provide additional assistance.

EYE

If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If dust is inhaled, remove from contaminated area.
- Encourage patient to blow nose to ensure clear passage of breathing.
- If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN

Treat symptomatically.

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Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog - Large fires only.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

FIRE/EXPLOSION HAZARD

- Solid which exhibits difficult combustion or is difficult to ignite.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
- Dry dust can also be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
- All movable parts coming in contact with this material should have a speed of less than 1-metre/sec.

Combustion products include: carbon monoxide (CO).

FIRE INCOMPATIBILITY

Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Personal Protective Equipment

Chemical splash suit.

Section 6 - ACCIDENTAL RELEASE MEASURES

EMERGENCY PROCEDURES

MINOR SPILLS

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Control personal contact by using protective equipment.

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Section 6 - ACCIDENTAL RELEASE MEASURES

- Use dry clean up procedures and avoid generating dust.
- Place in a suitable labelled container for waste disposal.

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Control personal contact by using protective equipment and dust respirator.
- Prevent spillage from entering drains, sewers or water courses.
- Avoid generating dust.
- Sweep, shovel up. Recover product wherever possible.
- Put residues in labelled plastic bags or other containers for disposal.
- If contamination of drains or waterways occurs, advise emergency services.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



X



X



+



X



X



+

+: May be stored together

O: May be stored together with specific precautions

X: Must not be stored together

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid generating and breathing dust
- Avoid contact with skin and eyes.
- Wear nominated personal protective equipment when handling.
- Use in a well-ventilated area.
- Use good occupational work practices.
- Observe manufacturer's storing and handling recommendations.

SUITABLE CONTAINER

Packaging as recommended by manufacturer.

- Check that containers are clearly labelled.

Plastic container.

STORAGE INCOMPATIBILITY

Avoid reaction with oxidising agents.

Heat and light accelerate decomposition.

Be sure container is tightly closed when not in use.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.

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Section 7 - HANDLING AND STORAGE

- Observe manufacturer's storing and handling recommendations.
- NOTE: Store in the dark.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- estrone:

CAS:53- 16- 7 CAS:37242- 41- 4

MATERIAL DATA

Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

PERSONAL PROTECTION



EYE

No special equipment needed when handling small quantities of substance.

For bulk handling wear:

Chemical goggles or
Face shield.

HANDS/FEET

Rubber gloves

PVC gloves

Protective shoe covers

Head covering.

OTHER

No special equipment when handling small quantities of substance otherwise:

Coveralls

For Emergencies:

Vinyl suit

Safety shower

RESPIRATOR

High Efficiency Dust Respirator (P2, P3)

For non-routine emergencies wear full face mask self-contained breathing apparatus.

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATOR

Protection Factor	Half- Face Respirator	Full- Face Respirator	Powered Air Respirator
10 x ES	P1 Air- line*	- -	PAPR- P1 -
50 x ES	Air- line**	P2	PAPR- P2
100 x ES	-	P3	-
		Air- line*	-
100+ x ES	-	Air- line**	PAPR- P3

* - Negative pressure demand ** - Continuous flow.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.

For further information consult

your

Occupational Health and Safety Advisor.

ENGINEERING CONTROLS

Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

When handling quantities up to 500 kilogram, work in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/containment technology.

Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.

Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional.

HEPA filtration of exhaust from dry product handling areas is required.

Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:

solvent, vapours, etc. evaporating from tank (in still air)

aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)

direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)

Air Speed:

0.25- 0.5 m/s (50- 100 f/min.)

0.5- 1 m/s (100- 200 f/min.)

1- 2.5 m/s (200- 500 f/min.)

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Within each range the appropriate value depends on:

Lower end of the range

- 1: Room air currents minimal or favourable to capture
- 2: Contaminants of low toxicity or of nuisance value only.
- 3: Intermittent, low production.
- 4: Large hood or large air mass in motion

Upper end of the range

- 1: Disturbing room air currents
- 2: Contaminants of high toxicity
- 3: High production, heavy use
- 4: Small hood- local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.

The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of:

- 10; high efficiency particulate (HEPA) filters or cartridges
- 10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator.
- 25-50; a full face-piece negative pressure respirator with HEPA filters
- 50-100; tight-fitting, full face-piece HEPA PAPR
- 100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Odourless, white crystalline solid; does not mix with water. Soluble in acetone, fixed oils, dioxane, pyridine, fixed alkaline hydroxide solutions and chloroform.

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

Molecular Weight: 270.37

Melting Range (°C): 258- 260

Solubility in water (g/L): Immiscible

pH (1% solution): Not available

Volatile Component (%vol): Negligible

Relative Vapour Density (air=1): Not available

Boiling Range (°C): Not available

Specific Gravity (water=1): Not available

pH (as supplied): Not applicable

Vapour Pressure (kPa): Negligible

Evaporation Rate: Not available

Flash Point (°C): Not available

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Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

Lower Explosive Limit (%): Not available
Autoignition Temp (°C): Not available
State: Divided solid

Upper Explosive Limit (%): Not available
Decomposition Temp (°C): Not available

log Kow (Sangster 1997): 3.13

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

Accidental ingestion of the material may be damaging to the health of the individual. The oestrogens may produce dose-related nausea and vomiting. The oestradiols and other oestrogens may cause undesirable uterine growth, proliferation and withdrawal bleeding or amenorrhoea (loss of period). The main effect of oestrogen exposure in the male is gynaemastia (enlargement of breasts). Other side-effects may include sodium retention, nitrogen retention, oedema, and weight gain, tenderness of the breasts, alterations in liver function, jaundice, depression, headache and dizziness. Large doses may cause premature closure of the epiphyses in the developing foetus or neonate. When employed in the treatment of metastatic malignant conditions the oestrogens may produce hypercalcaemia. Skin reactions may include facial hyperpigmentation (chloasma), rashes and hives (urticaria). Erythema multiforme has also been reported.

EYE

Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn). The dust may produce eye discomfort causing transient smarting, blinking.

SKIN

Skin contact with the material may damage the health of the individual; systemic effects may result following absorption. The material is not thought to be a skin irritant (i.e. is unlikely to produce irritant dermatitis as described in EC Directives using animal models). Temporary discomfort, however, may result from prolonged dermal exposures. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Toxic effects may result from skin absorption.

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INHALED

The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

On the basis of epidemiological data, the material is regarded as carcinogenic to humans. There is sufficient data to establish a causal association between human exposure to the material and the development of cancer.

Principal routes of exposure are by accidental skin and eye contact and inhalation of generated dusts.

When administered orally, topically, subcutaneously or by implantation, oestrone induced an increased incidence of mammary tumours in mice. In rats, subcutaneous injection or implantation of oestrone induced pituitary, adrenal and mammary tumours as well as bladder tumours in association with kidney stones. When administered subcutaneously, oestrone caused kidney tumours in both castrated and intact male hamsters.

Studies in humans show a strong association between use of the conjugated oestrogens and an increased incidence of endometrial carcinoma. In two studies, the use of intra-vaginal oestrogen was reported to induce increases of the incidence of endometrial cancer. Cases of liver tumours, including a hepatic adenoma in one woman and a haemangioendothelial sarcoma in one man, have been associated with the use of non-contraceptive oestrogens. In another study, the use of hormones during pregnancy, increased the risk of the development of testicular cancer (tumours included embryonal cell carcinomas, seminomas, teratomas, choriocarcinomas and interstitial cell carcinomas). There is conflicting evidence linking conjugated oestrogens and breast cancer. Rats fed conjugated oestrogens showed an increased incidence of mammary tumours (mainly fibroadenomas) and pituitary tumours in males, and thyroid carcinomas and pituitary tumours in females.

Studies indicate that the long-term administration of oestrogens may be associated with an increased incidence of endometrial cancer. In some studies post-menopausal users have been shown to be at significantly greater risk (4.5-13.9 times).

In males occupationally exposed to the oestrogens, chronic exposure may produce enlarged breasts (gynecomastia) and other feminising effects, nipple and areolar pigmentation, testicular atrophy, sterility, impotence and altered distribution of hair.

Exposed women may experience breast enlargement and menstrual disorders, premenstrual-like syndrome, endometrial cystic hyperplasia, increase in size of the uterine fibromyomata and cervical effects.

Even intermittent absorption of small amounts may result in relatively high systemic accumulation. Children born to exposed women show gynecomastia in boys and pseudoprecocious puberty in girls. Accelerated skeletal maturation, strong pigmentation of the sexual organs and feminising syndrome have been noted in children occupationally exposed in oestrogen production. A possible association exists with intrauterine exposure to female sex hormones and congenital anomalies such as heart defects and limb-reduction effects.

Repeated ingestion may produce nausea, vomiting, abdominal cramps, anorexia, colitis, headache, dizziness, irritability, depression, malaise, chorea and convulsions. Fluid and sodium retention, oedema, weight change, increased blood pressure, and increased risk of thromboembolic and thrombotic and cardiovascular disease, carbohydrate intolerance, liver

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Section 11 - TOXICOLOGICAL INFORMATION

function abnormalities, haemolytic uremic syndrome and a cystitis-like syndrome have also been reported. Long-term users may also show an increased incidence of gallstones, hyperlipidaemia, acute pancreatitis, aggravation of porphyria and effects on calcium and phosphorus metabolism.

The eye may develop neuro-ophthalmic lesions, steepening of corneal curvature with contact lens intolerance. Skin effects include itching, urticaria, dermatitis, increased pigmentation, photosensitivity, loss of scalp hair and hirsutism. Allergic reactions include erythema multiforme or nodosum and cholestatic jaundice. Susceptibility to candidiasis and libido changes may occur.

Application of oestrogen-containing cream has produced breast enlargement.

TOXICITY AND IRRITATION

No significant acute toxicological data identified in literature search.

Kidney tumours, leukaemia, lymphoma, paternal effects, maternal effects, effects on fertility, specific developmental effects (craniofacial), uterine tumours, effects on newborn, tumours at sites of application recorded.

IARC Cancer Review: Animal Sufficient Evidence

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Tenth Annual Report on Carcinogens: Substance known to be Carcinogenic

[National Toxicology Program: U.S. Dep. of Health and Human Services 2002].

Section 12 - ECOLOGICAL INFORMATION

log Kow (Sangster 1997): 3.13

No data for estrone.

Section 13 - DISPOSAL CONSIDERATIONS

- Recycle wherever possible. Special hazard may exist - specialist advice may be required.
- Consult manufacturer for recycling options.
- Consult State Land Waste Management Authority for disposal.
- Bury or incinerate residue at an approved site.
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
- Puncture containers to prevent re-use and bury at an authorised landfill.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM: None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS:UN, IATA, IMDG

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Section 15 - REGULATORY INFORMATION

REGULATIONS

estrone (CAS: 53-16-7) is found on the following regulatory lists;
OSPAR List of Substances of Possible Concern

No data available for estrone as CAS: 37242-41-4.

Section 16 - OTHER INFORMATION

INGREDIENTS WITH MULTIPLE CAS NUMBERS

Ingredient Name	CAS
estrone	53- 16- 7, 37242- 41- 4

The above information is believed to be accurate and represent the best information currently available to us, but does not represent any warranty expressed or implied of the properties of the product. User should make their own investigation to determine the suitability of the information for their particular purpose.

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