1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Estriol Formulation (Veterinary)

Manufacturer or supplier’s details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Carcinogenicity : Category 1A
Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (female reproductive organs, male reproductive organs, Blood, Kidney, Bladder)
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms :

Signal word : Danger
Hazard statements : H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H373 May cause damage to organs (female reproductive organs, male reproductive organs, Blood, Kidney, Bladder)
through prolonged or repeated exposure if swallowed. H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

**Prevention:**
P203 Obtain, read and follow all safety instructions before use.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P318 IF exposed or concerned, get medical advice.
P391 Collect spillage.

**Storage:**
P405 Store locked up.

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

Other hazards which do not result in classification:
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

**Chemical name** | **CAS-No.** | **Concentration (% w/w)**
---|---|---
Starch | 9005-25-8 | >= 10 - < 20
Oestriol | 50-27-1 | >= 1 - < 2.5

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**:
If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

**If swallowed**:
If swallowed, DO NOT induce vomiting.
5. FIREFIGHTING MEASURES

- **Suitable extinguishing media**: Water spray, Alcohol-resistant foam, Carbon dioxide (CO2), Dry chemical.
- **Unsuitable extinguishing media**: None known.
- **Specific hazards during firefighting**: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. 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**: 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. 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**: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- 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.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- 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.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Oestriol</td>
<td>50-27-1</td>
<td>TWA</td>
<td>0.5 μg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin
- Wipe limit 5 μg/100 cm²  | 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.

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

Particulates type

Hand protection

Material

Chemical-resistant gloves

Remarks

Consider double gloving.

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

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

powder

Colour

white

Odour

odourless
SAFETY DATA SHEET

Estriol Formulation (Veterinary)

Version 2.3  Revision Date: 10.10.2020  SDS Number: 1930655-00007  Date of last issue: 23.03.2020  Date of first issue: 07.09.2017

Odour Threshold : No data available
pH : 6
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
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 : Not applicable
Relative density : No data available
Density : 0.965 g/cm3
Solubility(ies)
   Water solubility : partly soluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
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:
- May form explosive dust-air mixture during processing, handling or other means.
  - Can react with strong oxidizing agents.
Conditions to avoid:
- Heat, flames and sparks.
  - Avoid dust formation.
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:

Starch:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Oestriol:
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg

Skin corrosion/irritation:
Not classified based on available information.

Serious eye damage/eye irritation:
Not classified based on available information.

Components:

Starch:
- Species: Rabbit
  - 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:

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

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

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

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

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Oral
Result: negative

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity**
May cause cancer.

**Components:**

**Oestriol:**
Species: Mouse
Application Route: Oral
Result: positive
Target Organs: Mammary gland

Species: Hamster
Application Route: Oral
Result: positive
Tumor Type: Kidney

Carcinogenicity - Assessment: Positive evidence from human epidemiological studies

**Reproductive toxicity**
May damage fertility. May damage the unborn child.

**Components:**

**Oestriol:**
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, female
Application Route: Oral
Fertility: LOAEL: 84 µg/kg
Result: Effects on fertility

Test Type: Fertility/early embryonic development
Species: Rat, female
Application Route: Subcutaneous
Fertility: LOAEL: 0.05 mg/kg body weight
Result: Effects on fertility

Test Type: Fertility/early embryonic development
Species: Rat, female
Application Route: Subcutaneous
Fertility: LOAEL: 100 mg/kg body weight
Result: Effects on fertility

Effects on foetal development:
Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 2 mg/kg body weight
Result: No embryo-foetal toxicity, Malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 4.5 mg/kg body weight
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Hamster
Application Route: Oral
Developmental Toxicity: LOAEL: 30 mg/kg body weight
Result: Embryo-foetal toxicity

Reproductive toxicity - Assessment:
Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.
Positive evidence of adverse effects on development from human epidemiological studies.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (female reproductive organs, male reproductive organs, Blood, Kidney, Bladder) through prolonged or repeated exposure if swallowed.

Components:

Oestriol:
Target Organs: Reproductive organs, Blood, Kidney, Bladder
Assessment: Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**Starch:**
- **Species:** Rat
- **NOAEL:** $\geq 2,000$ mg/kg
- **Application Route:** Skin contact
- **Exposure time:** 28 Days
- **Method:** OECD Test Guideline 410

**Oestriol:**
- **Species:** Dog
- **LOAEL:** 0.2 mg/kg
- **Application Route:** Oral
- **Exposure time:** 13 - 26 Weeks
- **Target Organs:** female reproductive organs, Blood, Kidney, Bladder

**Species:** Dog
- **LOAEL:** 8 mg/kg
- **Application Route:** Subcutaneous
- **Exposure time:** 1 yr
- **Target Organs:** male reproductive organs, female reproductive organs

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

**Components:**

**Oestriol:**
- **Ingestion:** Symptoms: breast tenderness, Nausea, Diarrhoea, Gastrointestinal disturbance, Dizziness, Headache, Vomiting, Hypertension, Oedema, effects on menstruation, gynecomastia, changes in vaginal secretions, visual disturbances, leg cramps, reduced libido

12. ECOLOGICAL INFORMATION

Ecotoxicity

**Components:**

**Oestriol:**
- **Toxicity to fish (Chronic toxicity):** NOEC: 0.000075 mg/l
- **Exposure time:** 100 d
- **Species:** Oryzias latipes (Japanese medaka)

- **M-Factor (Chronic aquatic toxicity):** 1,000
Persistence and degradability
No data available

Bioaccumulative potential
No data available

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Oestriol)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Oestriol)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Oestriol)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes
## Transport in bulk according to IMO instruments
Not applicable for product as supplied.

## Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

## 16. OTHER INFORMATION

### Further information
Sources of key data used to compile the Safety Data Sheet:

Date format: dd.mm.yyyy

Full text of other abbreviations:
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average

- AICL - Australian Inventory of Industrial Chemicals;
- ANTT - National Agency for Transport by Land of Brazil;
- ASTM - American Society for the Testing of Materials;
- bw - Body weight;
- CMR - Carcinogen, Mutagen or Reproductive Toxicant;
- DIN - Standard of the German Institute for Standardisation;
- DSL - Domestic Substances List (Canada);
- ECx - Concentration associated with x% response;
- ELx - Loading rate associated with x% response;
- EmS - Emergency Schedule;
- ENCS - Existing and New Chemical Substances (Japan);
- ErCx - Concentration associated with x% growth rate response;
- ERG - Emergency Response Guide;
- GHS - Globally Harmonized System;
- GLP - Good Laboratory Practice;
- IARC - International Agency for Research on Cancer;
- IATA - International Air Transport Association;
- IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk;
- IC50 - Half maximal inhibitory concentration;
- ICAO - International Civil Aviation Organization;
- IECSC - Inventory of Existing Chemical Substances in China;
- IMDG - International Maritime Dangerous Goods;
- IMO - International Maritime Organization;
- ISHL - Industrial Safety and Health Law (Japan);
- ISO - International Organisation for Standardization;
- KECI - Korea Existing Chemicals Inventory;
- LC50 - Lethal Concentration to 50% of a test population;
- LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose);
- MARPOL - International Convention for the Prevention of Pollution from Ships;
- n.o.s. - Not Otherwise Specified;
- Nch - Chilean Norm;
- NO(A)EC - No Observed (Adverse) Effect
Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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.

IN / EN