SAFETY DATA SHEET

Estriol Formulation (Veterinary)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Estriol Formulation (Veterinary)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300
Telefax : 908-735-1496

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Carcinogenicity, Category 1A
Reproductive toxicity, Category 1A
Specific target organ toxicity - repeated exposure, Category 2
Long-term (chronic) aquatic hazard, Category 1

H350: May cause cancer.
H360FD: May damage fertility. May damage the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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

Precautionary statements:

Prevention:
P201 Obtain special 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:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:
Oestriol

2.3 Other hazards
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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oestriol</td>
<td>50-27-1</td>
<td>200-022-2</td>
<td></td>
<td></td>
<td>Carc.1A; H350 Repr.1A; H360FD STOT RE1; H372 Aquatic Chronic1; H410</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1.000</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.
: Get medical attention.
: Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed
Risks
: May cause cancer.
: May damage fertility. May damage the unborn child.
: May cause damage to organs through prolonged or repeated exposure.

Contact with dust can cause mechanical irritation or drying of the skin.
: Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment
: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media
: None known.

5.2 Special hazards arising from the substance or mixture
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 prod-
: Carbon oxides
5.3 Advice for firefighters

- **Special protective equipment for firefighters**: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- **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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- **Personal precautions**: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

- **Environmental precautions**: Discharge into the environment must be avoided. 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.

6.3 Methods and material for containment and cleaning up

- **Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- **Technical measures**: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding
SAFETY DATA SHEET

Estriol Formulation (Veterinary)

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.
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.
Take care to prevent spills, waste and minimize release to the environment.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA OEL-RL (Respirable dust)</td>
<td>5 mg/m3</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Further information</td>
<td>Recommended Limit</td>
<td>TWA OEL-RL (inhalable dust)</td>
<td>10 mg/m3</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>
Further information | Recommended Limit
--- | ---
Oestriol 50-27-1 | TWA 0.5 µg/m³ (OEB 5) | Internal
Further information | Skin Wipe limit 5 µg/100 cm² | Internal

8.2 Exposure controls

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

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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.

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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder

Colour: white

Odour: odourless

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.

### 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)

<table>
<thead>
<tr>
<th>Water solubility</th>
<th>partly soluble</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### Auto-ignition temperature
: No data available

### Decomposition temperature
: No data available

### Viscosity

<table>
<thead>
<tr>
<th>Viscosity, kinematic</th>
<th>Not applicable</th>
</tr>
</thead>
</table>

### Explosive properties
: Not explosive

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

## 9.2 Other information

### Flammability (liquids)
: No data available

### Particle size
: No data available

---

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity
Not classified as a reactivity hazard.

#### 10.2 Chemical stability
Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

<table>
<thead>
<tr>
<th>Hazardous reactions</th>
<th>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</th>
</tr>
</thead>
</table>
10.4 Conditions to avoid

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials

Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:

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.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Species: Rat, female
Application Route: Subcutaneous
Fertility: LOAEL: 0,05 mg/kg body weight
Result: Effects on fertility

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.
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 through prolonged or repeated exposure.

Components:

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

Repeated dose toxicity

Components:

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, Gastroin-
Estriol Formulation (Veterinary)

SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**Oestradiol:**
- 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

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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.

SECTION 14: Transport information

14.1 UN number

**ADN** : UN 3077
**ADR** : UN 3077
**RID** : UN 3077
SAFETY DATA SHEET

Estriol Formulation (Veterinary)

Version 2.2  Revision Date: 09/13/2019  SDS Number: 1930401-00006  Date of last issue: 24.04.2019

IMDG: UN 3077
IATA: UN 3077

14.2 UN proper shipping name

ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Oestriol)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Oestriol)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Oestriol)
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Oestriol)
IATA: Environmentally hazardous substance, solid, n.o.s. (Oestriol)

14.3 Transport hazard class(es)

ADN: 9
ADR: 9
RID: 9
IMDG: 9
IATA: 9

14.4 Packing group

ADN
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9

ADR
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9
Tunnel restriction code: (-)

RID
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9

IMDG
Packing group: III
Labels: 9
EmS Code: F-A, S-F
IATA (Cargo)
Packing instruction (cargo aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

IATA (Passenger)
Environmentally hazardous: yes

IATA (Cargo)
Environmentally hazardous: yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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

AICS: not determined

DSL: not determined

IECSC: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.
SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-statements

H350: May cause cancer.
H360FD: May damage fertility. May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure if swallowed.
H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic: Long-term (chronic) aquatic hazard
Carc.: Carcinogenicity
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
ZA OEL: South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL: Long term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicaent; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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
SAFETY DATA SHEET

Estriol Formulation (Veterinary)

Version 2.2  
Revision Date: 09/13/2019  
SDS Number: 1930401-00006  
Date of last issue: 24.04.2019  
Date of first issue: 07.09.2017

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carc. 1A</td>
<td>H350</td>
</tr>
<tr>
<td>Repr. 1A</td>
<td>H360FD</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:

Calculation method

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.

ZA / EN