1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Estriol Formulation (Veterinary)

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
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

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:
P201 Obtain special instructions before use.
**SAFETY DATA SHEET**

**Estriol Formulation (Veterinary)**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.6</td>
<td>2020/10/10</td>
<td>1930390-00007</td>
<td>2020/03/23</td>
<td>2017/09/07</td>
</tr>
</tbody>
</table>

P202 Do not handle until all safety precautions have been read and understood.
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.

**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

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Oestriol</td>
<td>50-27-1</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>

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

**Most important symptoms:**
May cause cancer.
5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td>Dry chemical</td>
<td></td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
<tr>
<td>Specific hazards during firefighting</td>
<td>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.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>Carbon oxides</td>
</tr>
<tr>
<td>Specific extinguishing methods</td>
<td>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</td>
</tr>
<tr>
<td></td>
<td>Use water spray to cool unopened containers.</td>
</tr>
<tr>
<td></td>
<td>Remove undamaged containers from fire area if it is safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Evacuate area.</td>
</tr>
<tr>
<td>Special protective equipment for firefighters</td>
<td>In the event of fire, wear self-contained breathing apparatus.</td>
</tr>
<tr>
<td></td>
<td>Use personal protective equipment.</td>
</tr>
</tbody>
</table>

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>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</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: Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals. TWA 10 mg/m³ ACGIH Oestriol 0.5 µg/m³ (OEB 5) 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 face shield 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
10. STABILITY AND REACTIVITY

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
SAFETY DATA SHEET

Estriol Formulation (Veterinary)

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:
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Estriol Formulation (Veterinary)

| 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 Assessment | : Reproductive organs, Blood, Kidney, Bladder
| | : Causes damage to organs through prolonged or repeated exposure.
SAFETY DATA SHEET

Estriol Formulation (Veterinary)

Repeated dose toxicity

Components:

Starch:
Species: Rat
NOAEL: >= 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 (Oryzias latipes (Japanese medaka)): 0.000075 mg/l
Exposure time: 100 d

M-Factor (Chronic aquatic toxicity): 1,000

Persistence and degradability
No data available
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Estriol Formulation (Veterinary)

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 Annex II of MARPOL 73/78 and the IBC Code
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**

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazards substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

- Hazardous substances approved for use : Not applicable
- Prohibited substances : Not applicable
- Restricted substances : Not applicable

**Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials**

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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

- AICS : not determined
- DSL : not determined
- IECSC : not determined

### 16. OTHER INFORMATION

**Further information**


Date format : yyyy/mm/dd

**Full text of other abbreviations**
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.