

# **Estriol Formulation (Veterinary)**

Version Revision Date: SDS Number: Date of last issue: 04.12.2023 3.3 14.12.2023 1930395-00016 Date of first issue: 07.09.2017

# **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Estriol Formulation (Veterinary)

Other means of identification : Incurin (A008094)

**INCURIN (57787)** 

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1A

Specific target organ toxicity

- repeated exposure (Oral)

Category 1 (female reproductive organs, male reproductive or-

gans, Blood, Kidney, Bladder)

**GHS** label elements

Hazard pictograms



Signal Word : Danger

Hazard Statements : H350 May cause cancer.

H360FD May damage fertility. May damage the unborn child. H372 Causes damage to organs (female reproductive organs, male reproductive organs, Blood, Kidney, Bladder) through pro-

longed or repeated exposure if swallowed.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.



# **Estriol Formulation (Veterinary)**

Date of last issue: 04.12.2023 Version Revision Date: SDS Number: 3.3 14.12.2023 1930395-00016 Date of first issue: 07.09.2017

Response:

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

attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

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**

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch	9005-25-8	>= 10 -< 20
Oestriol	50-27-1	>= 1 -< 5

### **SECTION 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.

If in eyes, rinse well with water. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

May cause cancer.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

May damage fertility. May damage the unborn child.

Causes damage to organs through prolonged or repeated

exposure if swallowed.

Contact with dust can cause mechanical irritation or drying of

Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders First Aid responders should pay attention to self-protection,



# **Estriol Formulation (Veterinary)**

Version Revision Date: SDS Number: Date of last issue: 04.12.2023 3.3 14.12.2023 1930395-00016 Date of first issue: 07.09.2017

and use the recommended personal protective equipment

when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

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-

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 fire-fighters

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

Use personal protective equipment.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emer-

gency 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.



# **Estriol Formulation (Veterinary)**

Version Revision Date: SDS Number: Date of last issue: 04.12.2023 3.3 14.12.2023 1930395-00016 Date of first issue: 07.09.2017

#### **SECTION 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.

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.

Conditions for safe storage : Keep in properly labeled 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

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010- STPS-2014



# **Estriol Formulation (Veterinary)**

Version Revision Date: SDS Number: Date of last issue: 04.12.2023 3.3 14.12.2023 1930395-00016 Date of first issue: 07.09.2017

		TWA	10 mg/m <sup>3</sup>	ACGIH	
Oestriol	50-27-1	TWA	0.5 µg/m3 (OEB 5)	Internal	
	Further information: Skin				
		Wipe limit	5 μg/100 cm <sup>2</sup>	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

Hand protection

Particulates type

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.

# **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder, tablet

Color : white

Odor : odorless

Odor Threshold : No data available

pH : 6

Melting point/freezing point : No data available



# **Estriol Formulation (Veterinary)**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.12.2023

 3.3
 14.12.2023
 1930395-00016
 Date of first issue: 07.09.2017

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

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Density : 0.965 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : partly soluble

Partition coefficient: n-

octanol/water

Not applicable

Autoignition 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

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.



# **Estriol Formulation (Veterinary)**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.12.2023

 3.3
 14.12.2023
 1930395-00016
 Date of first issue: 07.09.2017

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous d

products

No hazardous decomposition products are known.

### **SECTION 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 sensitization

# Skin sensitization

Not classified based on available information.

### Respiratory sensitization

Not classified based on available information.

#### **Components:**

Starch:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig



# **Estriol Formulation (Veterinary)**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.12.2023

 3.3
 14.12.2023
 1930395-00016
 Date of first issue: 07.09.2017

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 - Assess-

ment

: 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.



# **Estriol Formulation (Veterinary)**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.12.2023

 3.3
 14.12.2023
 1930395-00016
 Date of first issue: 07.09.2017

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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 2 mg/kg body weight Result: No embryo-fetal toxicity., Malformations were

observed.

Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 4.5 mg/kg body weight

Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development

Species: Hamster Application Route: Oral

Developmental Toxicity: LOAEL: 30 mg/kg body weight

Result: Embryo-fetal toxicity.

Reproductive toxicity - As-

sessment

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

Causes 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.



# **Estriol Formulation (Veterinary)**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.12.2023

 3.3
 14.12.2023
 1930395-00016
 Date of first issue: 07.09.2017

### 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 y

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, Diarrhea, Gastroin-

testinal disturbance, Dizziness, Headache, Vomiting, hypertension, Edema, effects on menstruation, gynecomastia, changes in vaginal secretions, visual disturbances, leg

cramps, reduced libido

### **SECTION 12. ECOLOGICAL INFORMATION**

# **Ecotoxicity**

# **Components:**

**Oestriol:** 

Toxicity to fish (Chronic tox- : NOEC (Oryzias latipes (Japanese medaka)): 0.000075 mg/l

icity) Exposure time: 100 d

# Persistence and degradability

No data available

#### Bioaccumulative potential

No data available



# **Estriol Formulation (Veterinary)**

Date of last issue: 04.12.2023 Version Revision Date: SDS Number: 3.3 14.12.2023 1930395-00016 Date of first issue: 07.09.2017

Mobility in soil

No data available

Other adverse effects

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste Contaminated packaging

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**SECTION 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 Ш 9 Labels Environmentally hazardous yes

**IATA-DGR** 

UN/ID No. **UN 3077** 

Proper shipping name Environmentally hazardous substance, solid, n.o.s.

(Oestriol)

9 Class Ш Packing group

Miscellaneous Labels

956 Packing instruction (cargo

aircraft)

Packing instruction (passen-956

ger aircraft)

Environmentally hazardous yes

**IMDG-Code** 

**UN** number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Oestriol)

Class 9 Packing group Ш 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.



# **Estriol Formulation (Veterinary)**

Version Revision Date: SDS Number: Date of last issue: 04.12.2023 3.3 14.12.2023 1930395-00016 Date of first issue: 07.09.2017

### **Domestic regulation**

NOM-002-SCT

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Oestriol)

Class : 9
Packing group : III
Labels : 9

#### 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.

### **SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for

producing capsules, tablets and pills.

# The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 14.12.2023 Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average NOM-010-STPS-2014 / VLE- : Time weighted average limit value

PPT

AIIC - 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



# **Estriol Formulation (Veterinary)**

Version Revision Date: SDS Number: Date of last issue: 04.12.2023 3.3 14.12.2023 1930395-00016 Date of first issue: 07.09.2017

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; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8