

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 20/05/2014 Revision date: 07/11/2019 Supersedes: 06/07/2018 Version: 1.2

CLM-9147

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

1.1. Product identifier

Product form : Substance

Substance name : ESTRIOL (16 ALPHA-HYDROXYESTRADIOL) (2,3,4-13C3,99%) CHEMICAL PURITY 97%

EC-No. : 200-022-2 (Unlabeled)

 CAS-No.
 : 1255639-56-5

 Product code
 : CLM-9147

 Formula
 : *C3C15H24O3

Synonyms : 16alpha-Hydroxyestradiol

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

1.2.1. Relevant identified uses

No additional information available

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Cambridge Isotope Laboratories, Inc. 50 Frontage Road Andover, MA 01810

USA

USA: 1-800-322-1174 Int: 1-978-749-8000 <u>cilsales@isotope.com</u> www.isotope.com

Emergency telephone number

Emergency numbers:

Chemtrec: 1-800-424-9300 (24 hours) International: 1-703-741-5970 (24 hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Carc. 2 H351 Repr. 1A H360FD

Full text of hazard classes and H-statements : see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Carc.Cat.3; R40 Repr.Cat.1; R60 Repr.Cat.1; R61

Full text of R-phrases: see section 16

GHS-US classification

Carc. 2 H351 Repr. 1B H360

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Female reproductive system.

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2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H351 - Suspected of causing cancer (in contact with skin, if inhaled, if swallowed)

H360FD - May damage fertility. May damage the unborn child.

Precautionary statements (CLP) : P280 - Wear protective clothing, protective gloves.

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

P405 - Store locked up.

P501 - Dispose of contents/container to Comply with applicable regulations

GHS-US labeling

Hazard pictograms (GHS-US)



GHS08

Signal word (GHS-US) : Danger

Hazard statements (GHS-US) : H351 - Suspected of causing cancer (oral, Dermal, Inhalation)

H360 - May damage fertility or the unborn child (Dermal, Inhalation, oral)

Precautionary statements (GHS-US) : P201 - Obtain special instructions before use.

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

P280 - Wear protective gloves, protective clothing.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P405 - Store locked up.

P501 - Dispose of contents/container to Comply with applicable regulations

2.3. Other hazards

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
ESTRIOL (16 ALPHA-HYDROXYESTRADIOL) (2,3,4-13C3,99%) CHEMICAL PURITY 97%	(CAS-No.) 1255639-56-5 (EC-No.) 200-022-2 (Unlabeled)	100	Carc.Cat.3; R40 Repr.Cat.1; R60 Repr.Cat.1; R61
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
ESTRIOL (16 ALPHA-HYDROXYESTRADIOL) (2,3,4-	(CAS-No.) 1255639-56-5 (EC-No.) 200-022-2 (Unlabeled)	100	Carc. 2, H351 Repr. 1A, H360FD

Full text of R- and H- phrases: see section 16

Name	Product identifier	%	GHS-US classification
ESTRIOL (16 ALPHA-HYDROXYESTRADIOL) (2,3,4- 13C3,99%) CHEMICAL PURITY 97% (Main constituent)	(CAS-No.) 1255639-56-5	100	Carc. 2, H351 Repr. 1B, H360

Full text of H-phrases: see section 16

3.2. Mixtures

Not applicable

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SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of

dangerous area.

First-aid measures after inhalation : If breathed in, move person to fresh air. If not breathing, give artificial respiration. Consult a

physician.

First-aid measures after skin contact : Wash with soap and plenty of water. Consult a physician.

First-aid measures after eye contact : Flush eyes with water as a precaution.

First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a

physician.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : May be harmful if inhaled. May cause respiratory tract irritation.

Symptoms/effects after skin contact : May be harmful if absorbed through skin. May cause skin irritation.

Symptoms/effects after eye contact : May cause eye irritation.

Symptoms/effects after ingestion : May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Hazardous decomposition products formed under fire conditions: Carbon oxides.

6.1.1. For non-emergency personnel

Emergency procedures : Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure

adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3. Methods and material for containment and cleaning up

For containment : Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for

disposal.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate

exhaust ventilation at places where dust is formed. Normal measures for preventive fire

protection.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash hands before

breaks and at the end of workday.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at room temperature away from light and moisture.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protective equipment : Gloves. Protective clothing. Protective goggles. Self-contained breathing apparatus.



Eye protection : Wear safety glasses with side shields (or goggles) and a face shield.

: No data available

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous

substance at the work place.

Respiratory protection : When appropriate, use NIOSH/CEN approved respirator.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Solid

Molecular mass : 291.36 g/mol (Labeled)
Color : No data available
Odor threshold : No data available
pH : No data available
Relative evaporation rate (butyl acetate=1) : No data available

Melting point : 284 - 285 °C (543 - 545 °F)

Freezing point No data available No data available **Boiling point** Flash point : No data available No data available Auto-ignition temperature Decomposition temperature No data available Flammability (solid, gas) : No data available : No data available Vapor pressure Relative vapor density at 20 °C No data available Relative density No data available Solubility No data available Log Pow : No data available Log Kow No data available No data available Viscosity, kinematic Viscosity, dynamic : No data available : No data available Explosive properties Oxidizing properties No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Explosion limits

No additional information available

10.2. Chemical stability

Stable if stored under recommended conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

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10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Formed under fire conditions: Carbon oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

ESTRIOL (16 ALPHA-HYDROXYESTRADIOL) (16 ALPHA-HYDROXYESTRADIOL) (2,3,4-13C3,99%) CHEMICAL PURITY 97% (1255639-56-5)		
LD50 oral rat	> 2000 mg/kg		

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified

Carcinogenicity : There is limited evidence for the carcinogenicity of estriol in experimental animals. Studies in

humans strongly suggest that the administration of estrogens is causally related to an increased incidence of endometrial carcinoma; there is no evidence that estriol is different than

other estrogens in this respect. Limited evidence of carcinogenicity in animal studies.

Reproductive toxicity : Presumed human reproductive toxicant. May cause reproductive disorders.

Specific target organ toxicity – single exposure : Not classified Specific target organ toxicity – repeated : Not classified exposure

Aspiration hazard : Not classified

Symptoms/effects after inhalation : May be harmful if inhaled. May cause respiratory tract irritation.

Symptoms/effects after skin contact : May be harmful if absorbed through skin. May cause skin irritation.

Symptoms/effects after eye contact : May cause eye irritation.

Symptoms/effects after ingestion : May be harmful if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Waste materials should be disposed of under conditions which meet Federal, State, and local environmental control regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

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14.3. Additional information

Other information : No supplementary information available.

Special transport precautions : Not dangerous goods.

Overland transport

No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

14.4. Environmental hazards

Other information : No supplementary information available.

14.5. Special precautions for user

Special transport precautions : Not dangerous goods.

14.6. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

ESTRIOL (16 ALPHA-HYDROXYESTRADIOL) (2,3,4-13C3,99%) CHEMICAL PURITY 97% (1255639-56-5)	
SARA Section 311/312 Hazard Classes	Delayed (chronic) health hazard
SARA Section 313 - Emission Reporting	Not subject to reporting requirements of the United States SARA Section 313

15.2. International regulations

CANADA

ESTRIOL (16 ALPHA-HYDROXYESTRADIOL) (2,3,4-13C3,99%) CHEMICAL PURITY 97% (1255639-56-5)

Listed on the Canadian DSL (Domestic Substances List)

15.2.1. National regulations

No additional information available

15.3. US State regulations

ESTRIOL (16 ALPHA-HYDROXYESTRADIOL) (2,3,4-13C3,99%) CHEMICAL PURITY 97%(1255639-56-5)	
U.S California - Proposition 65 - Carcinogens List	Yes
U.S California - Proposition 65 - Developmental Toxicity	No
U.S California - Proposition 65 - Reproductive Toxicity - Female	No
U.S California - Proposition 65 - Reproductive Toxicity - Male	No
State or local regulations	U.S Pennsylvania - RTK (Right to Know) List U.S New Jersey - Right to Know Hazardous Substance List

SECTION 16: Other information

Other information

: This product is not radioactive. The data given for this product are those of the corresponding unlabeled compound, unless specifically indicated otherwise. Health and safety data for labeled compounds are generally not available, but are assumed to be similar or identical to the corresponding unlabeled compound.

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Full text of R-, H- and EUH-phrases:

Carc. 2	Carcinogenicity Category 2
Repr. 1A	Reproductive toxicity Category 1A
H351	Suspected of causing cancer
H360FD	May damage fertility. May damage the unborn child.
R40	Limited evidence of a carcinogenic effect
R60	May impair fertility
R61	May cause harm to the unborn child

NFPA health hazard : 0 - Materials that, under emergency conditions, would offer

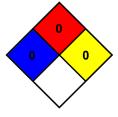
no hazard beyond that of ordinary combustible materials.

NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as

concrete, stone, and sand.

NFPA reactivity : 0 - Material that in themselves are normally stable, even

under fire conditions.



Hazard Rating

Health : 1 Slight Hazard - Irritation or minor reversible injury possible

Flammability : 0 Minimal Hazard Physical : 0 Minimal Hazard

CIL Substance SDS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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