



ASG Biochem Pvt. Ltd.

QUALITY CONTROL DEPARTMENT  
Ganganagar, 24 Parganas (N), West Bengal, PIN-700132  
P.O. GANGANAGAR, 24 PGS (N) W.B. PIN 700132 T + 91 033 2567 3236 / 3237  
Drug License No. DL-802-MB CIN: U24232DL2004PTC126594

## CERTIFICATE OF ANALYSIS

Product Name	ESTRIOL		
Batch No.	ESTZ01A011	Laboratory Reference No.	LAB/FG/23/160
Manufacturer	ASG BIOCHEM PVT. LTD.	Supplier	ASG BIOCHEM PVT. LTD.
Mfg. Date	NOVEMBER 2023	Retest Date	OCTOBER 2027
Batch Quantity	23000.00 gm.	Pharmacopoeia Reference	EP
Specification No.	ASG/SPEC/ESTZ/EP/01	STP No.	ASG/STP/ESTZ/EP/01
COA Issuance Date	01/12/2023		

Sl. No.	Test Parameters	Specification	Results
	CHARACTERS		
01.	Appearance	White or almost white crystalline powder	White, crystalline powder.
02.	Solubility	Practically insoluble in water, sparingly soluble in ethanol (96%), Practically insoluble in dichloromethane.	Practically insoluble in water, sparingly soluble in ethanol (96%), Practically insoluble in dichloromethane.
	IDENTIFICATION		
03.	A. Infrared absorption Spectrophotometry	Sample spectrum should be concordant with the spectrum of <i>Estriol CRS</i>	Sample spectrum concordant with the spectrum of reference standard (RS)
	B. Examine the chromatogram obtained in the Assay	The principal peak in the chromatogram obtained with test solution (b) is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c)	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
	C. Thin Layer Chromatography	The principal spot in the chromatogram obtained with the test solution is similar in position, colour in daylight, fluorescence in ultraviolet at 366 nm and size to the principle spot in the chromatogram obtained with the reference solution	The principal spot in the chromatogram obtained with the test solution is similar in position, colour in daylight, fluorescence in ultraviolet at 366 nm and size to the principle spot in the chromatogram obtained with the reference solution



ASG Biochem Pvt. Ltd.

QUALITY CONTROL DEPARTMENT  
P.O. GANGANAGAR, 24 PGS (N) W.B. PIN 700132  
Drug License No. DL-802-MB  
Ganganagar, 24 Parganas (N), West Bengal, PIN-700132  
T + 91 033 2567 3236 / 3237  
CIN: U24232DL2004PTC126594

## CERTIFICATE OF ANALYSIS

Product Name	ESTRIOL		
Batch No.	ESTZ01A011	Laboratory Reference No.	LAB/FG/23/160
Manufacturer	ASG BIOCHEM PVT. LTD.	Supplier	ASG BIOCHEM PVT. LTD.
Mfg. Date	NOVEMBER 2023	Retest Date	OCTOBER 2027
Batch Quantity	23000.00 gm.	Pharmacopoeia Reference	EP
Specification No.	ASG/SPEC/ESTZ/EP/01	STP No.	ASG/STP/ESTZ/EP/01
COA Issuance Date	01/12/2023		

Sl. No.	Test Parameters	Specification	Results
	<b>TESTS</b>		
04.	Specific Optical Rotation	+ 60° to + 65° (dried substance)	+ 62 °
05.	Loss on Drying	Maximum 0.5 per cent	0.12% (w/w)
06.	Assay (By Liquid Chromatography)	97.5 per cent to 102.0 per cent (dried substance)	99.5 % (w/w)
07.	Related Substance (By Liquid Chromatography)		
	Impurity F	Maximum 0.5 per cent	0.22% (a/a)
	Impurity E	Maximum 0.3 per cent	Not Detected
	Impurity A	Maximum 0.2 per cent	0.17% (a/a)
	Impurity D	Maximum 0.2 per cent	0.03% (a/a)
	Unspecified Impurities (for each impurity)	Maximum 0.10 per cent	0.06% at RRT 1.42
	Total	Maximum 1.0 per cent	0.48% (a/a)

Fecha Entrada: 29-08-2024

86404

ESTRIOL GRANEL



8 432780 864046

Lote: 0129904



[50-27-1]  
288,40  
C18H24O3

Bultos: 1

Guinama S.L.U.  
C/Oso, 3  
46165 La Pobla de Valbona (Spain)  
Tel: +34 96 186 99 90 - www.guinama.com

Guinama S.L.U.  
C/Oso, 3  
46165 La Pobla de Valbona (Spain)  
Tel: +34 96 186 99 90 - www.guinama.com



- PELIGRO.H351 Se sospecha que provoca cáncer.H360 Puede perjudicar la fertilidad o dañar al feto.H362 Puede perjudicar a los niños alimentados con leche materna.P201 Leer instrucciones especiales antes del usoP260 No respirar el polvo, el humo, el gas, la niebla, los vapores y el aerosol.P263 Evitar el contacto durante el embarazo/la lactancia.P264 Lavarse ... concienzudamente tras la manipulación.P280 Llevar guantes, prendas, gafas, máscara de protección.P308+P313 EN CASO DE exposición manifiesta o presunta: Consultar a un médico.P501 Eliminar el contenido, el recipiente en conformidad con la normativa local, regional, nacional o internacional.





ASG Biochem Pvt. Ltd.

QUALITY CONTROL DEPARTMENT  
P.O. GANGANAGAR, 24 PGS (N) W.B. PIN 700132  
Drug License No. DL-802-MB

Ganganagar, 24 Parganas (N), West Bengal, PIN-700132

T + 91 033 2567 3236 / 3237

CIN: U24232DL2004PTC126594

## CERTIFICATE OF ANALYSIS

Product Name	ESTRIOL		
Batch No.	ESTZ01A011	Laboratory Reference No.	LAB/FG/23/160
Manufacturer	ASG BIOCHEM PVT. LTD.	Supplier	ASG BIOCHEM PVT. LTD.
Mfg. Date	NOVEMBER 2023	Retest Date	OCTOBER 2027
Batch Quantity	23000.00 gm.	Pharmacopoeia Reference	EP
Specification No.	ASG/SPEC/ESTZ/EP/01	STP No.	ASG/STP/ESTZ/EP/01
COA Issuance Date	01/12/2023		

**Remarks:** In the opinion of the undersigned, the above mentioned product Meets/ Does not Meet the above test parameters as per specification.

**Storage Condition:** To be kept in well closed containers & stored at a temperature not exceeding 25°C.

**Additional Information:** Tested After micronization

	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY (QC)	K. B. MISHRA	Sr. SUPERVISOR		01/12/2023
CHECKED BY (QC)	P. BASU	EXECUTIVE		01/12/2023
APPROVED BY (QC)	I. BHATTACHARYYA	MANAGER		01/12/2023
APPROVED BY (QA)	A. BANERJEE	Sr. EXECUTIVE		01/12/2023



ASG Biochem Pvt. Ltd.

QUALITY CONTROL DEPARTMENT  
P.O. GANGANAGAR, 24 PGS (N) W.B. PIN 700132  
Drug License No. DL-802-MB  
Ganganagar, 24 Parganas (N), West Bengal, PIN-700132  
T + 91 033 2567 3236 / 3237  
CIN: U24232DL2004PTC126594

## CERTIFICATE OF ANALYSIS

Product Name	ESTRIOL		
Batch No.	ESTZ01A011	Laboratory Reference No.	LAB/FG/23/160
Manufacturer	ASG BIOCHEM PVT. LTD.	Supplier	ASG BIOCHEM PVT. LTD.
Mfg. Date	NOVEMBER 2023	Retest Date	OCTOBER 2027
Batch Quantity	23000.00 gm.	Pharmacopoeia Reference	EP
Specification No.	ASG/SPEC/ESTZ/EP/01	STP No.	ASG/STP/ESTZ/EP/01
COA Issuance Date	01/12/2023		

Additional Tests			
Sl. No.	Test Parameters	Specification	Results
01	Particle Size	Report Value	90% < 10µm

**Remarks:** In the opinion of the undersigned, the above mentioned product Meets/ Does-not Meet the above test parameters as per specification.

**Storage Condition:** To be kept in well closed containers & stored at a temperature not exceeding 25°C.

**Additional Information:** Tested After micronization

	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY (QC)	K. B. MISHRA	Sr. SUPERVISOR	K. B. Mishra	01/12/2023
CHECKED BY (QC)	P. BASU	EXECUTIVE	P. Basu	01/12/2023
APPROVED BY (QC)	I. BHATTACHARYYA	MANAGER	I. Bhattacharyya	01/12/2023
APPROVED BY (QA)	A. BANERJEE	Sr. EXECUTIVE	A. Banerjee	01/12/2023



ASG Biochem Pvt. Ltd.

QUALITY CONTROL DEPARTMENT  
Ganganagar, 24 Parganas (N), West Bengal, PIN-700132  
P.O. GANGANAGAR, 24 PGS (N) W.B. PIN 700132  
T + 91 033 2567 3236 / 3237  
Drug License No. DL-802-MB  
CIN: U24232DL2004PTC126594

## CERTIFICATE OF ANALYSIS

Product Name	ESTRIOL		
Batch No.	ESTZ01A011	Laboratory Reference No.	LAB/FG/23/160
Manufacturer	ASG BIOCHEM PVT. LTD.	Supplier	ASG BIOCHEM PVT. LTD.
Mfg. Date	NOVEMBER 2023	Retest Date	OCTOBER 2027
Batch Quantity	23000.00 gm.	Pharmacopoeia Reference	EP
Specification No.	ASG/SPEC/ESTZ/EP/01	STP No.	ASG/STP/ESTZ/EP/01
COA Issuance Date	01/12/2023		

Sl. No.	Test Parameters	Specification	Results
01	Microbiological Tests	Total Aerobic Microbial Count: NMT 1000 cfu/gm	20 cfu/gm
		Total Yeast Mould Count: NMT 100 cfu/gm	NIL

**Remarks:** In the opinion of the undersigned, the above mentioned product Meets/ Does not Meet the above test parameters as per specification.

**Storage Condition:** To be kept in well closed containers & stored at a temperature not exceeding 25°C.

**Additional Information:** Tested After micronization

	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY (QC)	K. B. MISHRA	Sr. SUPERVISOR	K. B. Mishra	01/12/2023
CHECKED BY (QC)	P. BASU	EXECUTIVE	P. Basu	01/12/2023
APPROVED BY (QC)	I. BHATTACHARYYA	MANAGER	I. Bhattacharyya	01/12/2023
APPROVED BY (QA)	A. BANERJEE	Sr. EXECUTIVE	A. Banerjee	01/12/2023



ASG Biochem Pvt. Ltd.

QUALITY CONTROL DEPARTMENT, Ganganagar, 24 Parganas (N), West Bengal, PIN-700132  
P.O. GANGANAGAR, 24 PGS (N) W.B. PIN 700132 T + 91 033 2567 3236 / 3237  
Drug License No. DL-802-MB CIN: U24232DL2004PTC126594

## CERTIFICATE OF ANALYSIS

Product Name	ESTRIOL		
Batch No.	ESTZ01A011	Laboratory Reference No.	LAB/FG/23/160
Manufacturer	ASG BIOCHEM PVT. LTD.	Supplier	ASG BIOCHEM PVT. LTD.
Mfg. Date	NOVEMBER 2023	Retest Date	OCTOBER 2027
Batch Quantity	23000.00 gm.	Pharmacopoeia Reference	EP
Specification No.	ASG/SPEC/ESTZ/EP/01	STP No.	ASG/STP/ESTZ/EP/01
COA Issuance Date	01/12/2023		

Additional Tests			
Sl. No.	Test Parameters	Specification	Results
01.	Residual Solvents: (By GC)		
	Dimethylformamide	NMT 880 ppm	Not Detected
	Methanol	NMT 3000 ppm	236 ppm
	1,2-Dichloroethane	NMT 5 ppm	Not Detected
	Ethyl Acetate	NMT 5000 ppm	Not Detected
	Ethanol	NMT 5000 ppm	59 ppm
	Acetone	NMT 5000 ppm	152 ppm

**Remarks:** In the opinion of the undersigned, the above mentioned product Meets/ ~~Does not Meet~~ the above test parameters as per specification.

**Storage Condition:** To be kept in well closed containers & stored at a temperature not exceeding 25°C.

**Additional Information:** Tested After micronization

	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY (QC)	K. B. MISHRA	Sr. SUPERVISOR	K. B. Mishra	01/12/2023
CHECKED BY (QC)	P. BASU	EXECUTIVE	P. Basu	01/12/2023
APPROVED BY (QC)	I. BHATTACHARYYA	MANAGER	I. Bhattacharyya	01/12/2023
APPROVED BY (QA)	A. BANERJEE	Sr. EXECUTIVE	A. Banerjee	01/12/2023



ASG Biochem Pvt. Ltd.

QUALITY CONTROL DEPARTMENT  
P.O. GANGANAGAR, 24 PGS (N) W.B. PIN 700132  
Drug License No. DL-802-MB  
T + 91 033 2567 3236 / 3237  
CIN: U24232DL2004PTC126594

## CERTIFICATE OF ANALYSIS

Product Name	ESTRIOL		
Batch No.	ESTZ01A011	Laboratory Reference No.	LAB/FG/23/160
Manufacturer	ASG BIOCHEM PVT. LTD.	Supplier	ASG BIOCHEM PVT. LTD.
Mfg. Date	NOVEMBER 2023	Expiry Date	OCTOBER 2027
Batch Quantity	23000.00 gm.	Pharmacopoeia Reference	EP
Specification No.	ASG/SPEC/ESTZ/EP/01	STP No.	ASG/STP/ESTZ/EP/01
COA Issuance Date	01/12/2023		

Additional Tests			
Sl. No.	Test Parameters	Specification	Results
01.	Elemental Analysis		
	Lead	NMT 0.5 µg/g	0.2 ppm
	Cadmium	NMT 0.5 µg/g	0.0 ppm
	Arsenic	NMT 1.5 µg/g	0.0 ppm
	Mercury	NMT 3 µg/g	0.0 ppm
	Cobalt	NMT 5 µg/g	0.0 ppm
	Vanadium	NMT 10 µg/g	0.0 ppm
	Nickel	NMT 20 µg/g	0.11 ppm
	Lithium	NMT 55 µg/g	0.0 ppm


Remarks: In the opinion of the undersigned, the above mentioned product Meets/ Does-not-Meet the above test parameters as per specification.

Storage Condition: Preserve in tight containers protected from light and store at a temperature not exceeding 25°C

Additional Information: Tested After micronization

	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY (QC)	K. B. MISHRA	Sr. SUPERVISOR	K. B. Mishra	01/12/2023
CHECKED BY (QC)	P. BASU	EXECUTIVE	P. Basu	01/12/2023
APPROVED BY (QC)	I. BHATTACHARYYA	MANAGER	I. Bhattacharyya	01/12/2023
APPROVED BY (QA)	A. BANERJEE	Sr. EXECUTIVE	A. Banerjee	01/12/2023



	<b>ASG BIOCHEM PRIVATE LIMITED</b> <b>Ganganagar, 24 PGS (N), West Bengal, India.</b>	
	<b>MATERIAL SAFETY DATA SHEET</b> ( According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 )	
<b>Product Name : ESTRIOL (BP/USP/ Ph. Eur)</b>	<b>Version: 8.0</b>	<b>Page 1 of 10</b>

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

### 1.1. Product identifier

Product form	: Substance
Substance name	: Estriol
Chemical name	: Estriol
Product code	: 74662114

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

#### 1.2.1. Relevant identified uses

Main use category	: The product is intended for research, analysis and scientific education.
Use of the substance/mixture	: For professional use only
Function or use category	: Laboratory chemicals

#### 1.2.2. Uses advised against

Restrictions on use	: Do not use : Ingestion, Inhalation, Dermal
---------------------	--

### 1.3. Details of the supplier of the safety data sheet

Manufacturer / Supplier :	ASG Biochem Pvt. Ltd. Ganganagar, 24 Parganas (N), Kolkata-700132
Telephone:	033-2567-2813
Service hours:	Monday to Friday, 9 am to 6 pm (Standard time zone GMT +5.30 hrs)

### 1.4. Emergency telephone number

Emergency number	: 033-2567-2813
------------------	-----------------

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

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

Carcinogenicity, Category 1A	H350	
Reproductive toxicity, Category 1A	H360FD	
Specific target organ toxicity – Repeated exposure, Category 1	H372	
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410	(M=1000)

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

### 2.2. Label elements

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

Hazard pictograms (CLP)



GHS08

GHS09

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H350 - May cause cancer.

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


H372 - Causes damage to organs (genital organs, blood, kidneys, urinary bladder) through prolonged or repeated exposure (oral).

H410 - Very toxic to aquatic life with long lasting effect

ASG BIOCHEM PVT. LTD.

11/07/2024  
Authorised Signatories



	<b>ASG BIOCHEM PRIVATE LIMITED</b> <b>Ganganagar, 24 PGS (N), West Bengal, India.</b>	
	<b>MATERIAL SAFETY DATA SHEET</b> ( According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 )	
<b>Product Name : ESTRIOL (BP/USP/ Ph. Eur)</b>	<b>Version: 8.0</b>	<b>Page 2 of 10</b>

Precautionary statements (CLP)

- : P201 - Obtain special instructions before use.  
 P202 - Do not handle until all safety precautions have been read and understood.  
 P260 - Do not breathe dust/fume/gas/mist/vapours/spray.  
 P264 - Wash hands, forearms and face thoroughly after handling.  
 P270 - Do not eat, drink or smoke when using this product.  
 P273 - Avoid release to the environment.  
 P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
 P314 - Get medical advice/attention if you feel unwell.  
 P391 - Collect spillage.  
 P405 - Store locked up.  
 P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP)



GHS08

### 2.3. Other hazards

No additional information available


## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008[CLP]
Estriol	-	≤ 100	Carc. 1A, H350 Repr. 1A, H360FD STOT RE 1, H372 Aquatic Chronic 1, H410 (M=1000)

ASG BIOCHEM PVT. LTD.

*[Signature]*  
 11/07/2024  
 Authorised Signatories

	<b>ASG BIOCHEM PRIVATE LIMITED</b> Ganganagar, 24 PGS (N), West Bengal, India.	
	<b>MATERIAL SAFETY DATA SHEET</b> (According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878)	
<b>Product Name : ESTRIOL (BP/USP/ Ph. Eur)</b>	<b>Version: 8.0</b>	<b>Page 3 of 10</b>

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: Move to fresh air. Allow affected person to breathe fresh air.
First-aid measures after skin contact	: Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent.
First-aid measures after eye contact	: Rinse with water while holding the eyes wide open.
First-aid measures after ingestion	: Rinse mouth. Specific medical surveillance. Prolonged medical observation may be indicated.

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

Symptoms/effects	: Delayed adverse effects possible.
Symptoms/effects after inhalation	: Insufficient data available.
Symptoms/effects after skin contact	: Insufficient data available.
Symptoms/effects after eye contact	: Insufficient data available.
Symptoms/effects after ingestion	: Symptoms may include dizziness, headache, nausea and loss of coordination.

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

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active substance. Pharmaceutical.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Extinguishing blanket.

### 5.2. Special hazards arising from the substance or mixture


Fire hazard : See Heading 2.2.

### 5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

ASG BIOCHEM PVT. LTD.

  
11/07/2024  
Authorized Signatories

	<b>ASG BIOCHEM PRIVATE LIMITED</b> Ganganagar, 24 PGS (N), West Bengal, India.	
	<b>MATERIAL SAFETY DATA SHEET</b> (According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878)	
<b>Product Name : ESTRIOL (BP/USP/ Ph. Eur)</b>	<b>Version: 8.0</b>	<b>Page 4 of 10</b>

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.
- 6.1.1. For non-emergency personnel  
Emergency procedures : Wear suitable protective clothing, gloves and eye or face protection.
- 6.1.2. For emergency responders  
No additional information available

### 6.2. Environmental precautions

No additional information available

### 6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with : Sodium hypochlorite solution.

### 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 : The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.
- Precautions for safe handling : Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Comply with applicable regulations.
- Storage conditions : Store locked up.

### 7.3. Specific end use(s)

See Heading 1.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters:

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2 Recommended monitoring procedures

No additional information available

#### 8.1.3 Air contaminants formed

No additional information available

#### 8.1.4 DNEL and PNEC

No additional information available


#### 8.1.5 Control banding

No additional information available

ASG BIOCHEM PVT. LTD.

*11/07/2024*

Authorised Signatories

	<b>ASG BIOCHEM PRIVATE LIMITED</b> <b>Ganganagar, 24 PGS (N), West Bengal, India.</b>	
	<b>MATERIAL SAFETY DATA SHEET</b> ( According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 )	
<b>Product Name : ESTRIOL (BP/USP/ Ph. Eur)</b>	<b>Version: 8.0</b>	<b>Page 5 of 10</b>

## 8.2. Control parameters: Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Safety glasses. DIN EN 166

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Use chemically protective clothing. DIN EN 13034

##### Hand protection:

Chemically resistant protective gloves. ISO 374-1

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

No additional information available


## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Not available
Appearance	: Powder.
Odour	: Not applicable.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: < 0.1 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

ASG BIOCHEM PVT. LTD.

11/07/2024  
Authorized Signatory

	<b>ASG BIOCHEM PRIVATE LIMITED</b> Ganganagar, 24 PGS (N), West Bengal, India.	
	<b>MATERIAL SAFETY DATA SHEET</b> (According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878)	
<b>Product Name : ESTRIOL (BP/USP/ Ph. Eur)</b>	<b>Version: 8.0</b>	<b>Page 6 of 10</b>

## 9.2. Other information

### 9.2.1. Information with regard to physical hazard classes

No additional information available

### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under normal conditions.

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

None under normal use. See Section 7.

### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)


#### Estriol

LD50 oral rat	> 2000 mg/kg RTECS No: KG8225000
---------------	----------------------------------

Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: <del>May cause cancer.</del>
Reproductive toxicity	: May damage fertility. May damage the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Causes damage to organs (genital organs, blood, kidneys, urinary bladder) through prolonged or repeated exposure (oral).
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

ASG BIOCHEM PVT. LTD.

11/07/2024  
Authorized Signature

	<b>ASG BIOCHEM PRIVATE LIMITED</b> Ganganagar, 24 PGS (N), West Bengal, India.	
	<b>MATERIAL SAFETY DATA SHEET</b> (According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878)	
<b>Product Name : ESTRIOL (BP/USP/ Ph. Eur)</b>	<b>Version: 8.0</b>	<b>Page 7 of 10</b>

#### 11.2. Information on other hazards

No additional information available

### SECTION 12: Ecological Information

#### 12.1. Toxicity

Ecology – general : Hazardous waste. Use suitable disposal containers.  
Hazardous to the aquatic environment, short-term : Not classified  
(acute)  
Hazardous to the aquatic environment, long-term : Very toxic to aquatic life with long lasting effects  
(chronic)

<b>Estriol</b>	
NOEC chronic fish	0.000075 mg/l (100 days, Oryzias latipes (Ricefish))

#### 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. Endocrine disrupting properties

No additional information available

#### 12.7. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

### SECTION 14: Transport information

In accordance with ADR / IMDG / IATA


ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
UN 3077	UN 3077	UN 3077

ASG BIOCHEM PVT. LTD.

*[Signature]*

11/07/2024

Authorised Signatories

	<b>ASG BIOCHEM PRIVATE LIMITED</b> <b>Ganganagar, 24 PGS (N), West Bengal, India.</b>	
	<b>MATERIAL SAFETY DATA SHEET</b> (According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878)	
<b>Product Name : ESTRIOL (BP/USP/ Ph. Eur)</b>	<b>Version: 8.0</b>	<b>Page 9 of 10</b>

Special provisions (IMDG)	: 274, 335, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP02, P002
Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: BK1, BK2, BK3, T1
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-F
Stowage category (IMDG)	: A
Stowage and handling (IMDG)	: SW23
<b>Air transport</b>	
PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	:
Y956 PCA limited quantity max net quantity (IATA)	:
30kgGPCA packing instructions (IATA)	:
956	:
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197, A215
ERG code (IATA)	: 9L

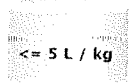

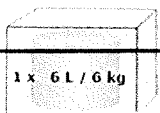
#### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

### Environmental Hazardous Substances –Exemption

IATA-DGR contains a special provision A197 requiring the exemption of materials UN 3077

The material are exempt when the net quantity per individual package does not exceed 5Kg (solids) or 5L (liquids), and where the packaging corresponds to the general requirements. In practice this means:

		Declaration required
Individual container		NO
Combined packaging		NO
Combined packaging		YES

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations


REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

ASG BIOCHEM PVT. LTD.

*(Signature)*  
 11/07/2024  
 Authorised Signatory



	<b>ASG BIOCHEM PRIVATE LIMITED</b> Ganganagar, 24 PGS (N), West Bengal, India.	
	<b>MATERIAL SAFETY DATA SHEET</b> (According to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878)	
<b>Product Name : ESTRIOL (BP/USP/ Ph. Eur)</b>	<b>Version: 8.0</b>	<b>Page 10 of 10</b>

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

## 15.2. Chemical safety assessment

No additional information available

### SECTION 16: Other Information

Full text of H- and EUH-statements:	
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Carc. 1A	Carcinogenicity, Category 1A
H350	May cause cancer.
H360FD	May damage fertility. May damage the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
Repr. 1A	Reproductive toxicity, Category 1A
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Authorized Signatory:

Name :

Designation:

Sign & Date:

ASG BIOCHEM PVT. LTD.

*[Signature]*  
11/07/2024

Authorized Signatories

**MULTIMODAL DANGEROUS GOODS FORM**

This form may be used as a dangerous goods declaration as it meets the requirements of SOLAS, chapter VII, regulation 4;  
MARPOL, Annex III, Regulation 4.

<b>1 Sender</b>  <b>FLAVINE PHARMA FRANCE</b> <b>3 VOIE D'ALLEMAGNE</b> <b>13127 VITROLLES</b> <b>FRANCE</b>		<b>2 Transport document number</b>				
		<b>3 Page No 1 of 1</b>	<b>4 Shipper's reference</b> SFPF002139			
		<b>5 Freight Forwarder's Reference</b>				
<b>6 Consignee</b>		<b>7 Carrier (to be completed by the carrier)</b>				
<b>GUINAMA S.L.</b> <b>C/ Praga s/n (Pol. Ind. Gutenberg)</b> <b>La Pobla de Vallbona 46185</b> <b>Spain</b>		<b>SHIPPER'S DECLARATION</b> I hereby declare that the contents of this consignment are fully and accurately described below by the Proper Shipping Name, and are classified, packaged, marked and labelled/placarded and are in all respects in proper condition for transport according to the applicable international and national governmental regulations.				
<b>8 This shipment is within the limitations prescribed for:-</b> (Delete non Applicable)  <table border="1"> <tr> <td>Passenger and Cargo Aircraft</td> <td>Cargo Aircraft Only</td> </tr> </table>		Passenger and Cargo Aircraft	Cargo Aircraft Only	<b>9 Additional handling information</b>		
Passenger and Cargo Aircraft	Cargo Aircraft Only					
<b>10 Vessel</b>	<b>11 Port/Place of loading</b> 13127 Vitrolles, France					
<b>12 Port/Place of discharge</b> 46185 La Pobla de Vallbona Spain	<b>13 Destination</b> 08020 La Pobla de Vallbona Spain					
<b>14 Shipping Marks</b>	<b>*Number and kind of packages: description of goods</b>	<b>Gross mass (kg)</b>	<b>Net mass (kg)</b>	<b>Cube (m³)</b>		
1 kg Estriol In 1 X 1 KG NET TIN ADR UN3077 (Environmentally Hazardous Substance, Solid, NOS) Class 9, Packing Group III  <b>DANGEROUS GOODS IN LIMITED QUANTITY</b>		3 kg	1 kg			
<b>15 Container identification number / vehicle registration no.</b>	<b>16. Seal number(s)</b>	<b>17 Container / Vehicle size &amp; type</b>	<b>18 Tare mass (kg)</b>	<b>19 Total gross mass (including tare) (kg)</b>		
<b>CONTAINER/VEHICLE PACKING CERTIFICATE</b> I hereby declare that the goods described above have been packed/loaded into the container/vehicle identified above in accordance with the applicable provisions ** <b>MUST BE COMPLETED AND SIGNED FOR ALL CONTAINER / VEHICLE LOADS BY PERSON RESPONSIBLE FOR PACKING / LOADING</b>		<b>21 RECEIVING ORGANISATION RECEIPT</b> Received the above number of packages/containers/trailers in apparent good order and condition, unless stated hereon: RECEIVING ORGANISATION REMARKS:				
<b>20 Name of Company</b>  FLAVINE PHARMA FRANCE		<b>Haulier's Name</b>	<b>22 Name of company (OF SHIPPER PREPARING THIS NOTE)</b> FLAVINE PHARMA FRANCE			
<b>Name/status of declarant</b> Elisabeth DUMAS, Logistic Manager		<b>Vehicle Registration No.</b>	<b>Name/status of declarant</b> Elisabeth DUMAS, logistic Manager			
<b>Place and Date</b>  13127 Vitrolles, FRANCE 23.08.2024		<b>Signature and date</b>	<b>Place and date</b> 13127 Vitrolles, FRANCE, 23.08.2024			
<b>Signature of declarant</b>  ESU		<b>DRIVER'S SIGNATURE</b>	<b>Signature of Declarant</b>			

**\* DANGEROUS GOODS**

You must specify: UN No., Proper Shipping name, hazard class, packing group, (where assigned), marine pollutant and observe the mandatory requirements under applicable national and international governmental regulations. For the purposes of the IMDG Code see 5.4.1.4

\*\* For the purposes of the IMDG Code see 5.4.2. This form is reproduced from IMDG code (amendment 37-14), Chapter 5.4 – Documentation, Page 275

**FLAVINE**  
 Pharmatransport Solutions  
 3 voie d'Allemagne  
 13127 Vitrolles - France  
 Tel : +33 4 42 87 55 35

Siret : 538 503 756 00032 - APE 4646Z