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

Catalogue Number	CS-O-59188
Product Name	Levonorgestrel Impurity 3
CAS No.	178737-52-5
Category	Impurity
Synonyms	(8R,9S,10R,13S,14S,17S)-13-ethyl-17-ethynyl-17-hydroxy-1,2,6,7,8,9,10,11,12,13,14,15,16,17-tetradecahydro-3H-cyclopenta[a]phenanthren-3-one
Brand	Clearsynth Labs Ltd.
Identified uses	Laboratory Chemicals
Uses advised against	Not available
Company	Clearsynth Labs Ltd. Mumbai, India
Emergency Phone #	+91-22-245045900
REACH No.	Not available

SECTION 2: Hazards identification

Disclaimer: This is sample MSDS. Please email **sales@clearsynth.com** for more details.

2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Skin irritation (Category 2)
Serious eye damage/eye irritation (Category 2)

2.2 Label Elements

Signal Word: Warning

Hazard Statement(s)

Code	Statement
H315	Causes skin irritation.
H319	Causes serious eye irritation.

H351	Not available
H360	Not available
H362	Not available
H400	Not available
H410	Not available

Precautionary Statement(s)

Code	Statement
P203	Not available
P260	Not available
P263	Not available
P264	Wash hands thoroughly after handling.
P264+P265	Not available
P270	Not available
P273	Not available
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if presen
P318	Not available
P321	Specific treatment (see … on this label).
P332+P317	If skin irritation occurs: Get medical help.
P337+P317	If eye irritation persists: Get medical help.
P362+P364	Take off contaminated clothing and wash it before reuse.
P391	Not available
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulatio

SECTION 3: Composition / information on ingredients

3.1 Substance

Component : Levonorgestrel Impurity 3
CAS Number : 178737-52-5

Molecular Formula : C21H28O2
Molecular Weight : 312.45
Parent Chemical : Levonorgestrel
Synonyms : (8R,9S,10R,13S,14S,17S)-13-ethyl-17-ethynyl-17-hydroxy-1,2,6,7,8,9,10,11,12,13,14,15,16,17-tetradecahydro-3H-cyclopenta[a]phenanthren-3-one
Concentration : Not available

SECTION 4: First aid measures

SECTION 4: First-aid measures

4.1 Description of first aid measures
General advice: Seek medical attention if symptoms occur or persist. Show this SDS to the physician.
Inhalation: Move person to fresh air. If breathing is difficult, seek medical attention.
Skin contact: Wash with soap and water. Remove contaminated clothing and wash before reuse. Get medical attention if irritation develops.
Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Seek medical attention if irritation persists.
Ingestion: Rinse mouth. Do not induce vomiting unless directed by medical personnel. Seek medical attention.

4.2 Most important symptoms/effects, acute and delayed
Not available.

4.3 Indication of immediate medical attention and special treatment needed
Treat symptomatically. No data available.

SECTION 5: Firefighting measures

SECTION 5: Fire-fighting measures

5.1 Extinguishing media
Suitable extinguishing media: Use extinguishing measures appropriate to local circumstances and the surrounding environment (e.g., water spray, dry chemical, foam, carbon dioxide).
Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance or mixture
Hazardous combustion products: Not available. Thermal decomposition may produce irritating and/or toxic fumes.

5.3 Advice for firefighters
Wear self-contained breathing apparatus (SCBA) and full protective gear. Use water spray to cool unopened containers exposed to heat. Avoid inhalation of combustion products.

SECTION 6: Accidental release measures

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Avoid breathing dust. Avoid contact with skin and eyes. Use appropriate personal protective equipment (see Section 8). Ensure adequate ventilation.

6.2 Environmental precautions

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Do not allow to enter drains/surface waters/groundwater.

6.3 Methods and material for containment and cleaning up
Contain spill. Collect spilled material using methods that minimize dust generation (e.g., damp wipe or HEPA-filtered vacuum). Place in a suitable, closed container for disposal. Clean contaminated area.

6.4 Reference to other sections
See Section 8 for personal protective equipment and Section 13 for disposal considerations.

SECTION-7: Handling and storage

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Handle in accordance with good industrial hygiene and safety practice. Avoid formation of dust and aerosols. Avoid contact with skin, eyes, and clothing. Do not breathe dust. Use with adequate ventilation. Wash hands thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities
Store tightly closed in original container in a cool, dry, well-ventilated place. Protect from moisture. Keep away from incompatible materials.
Incompatible materials: Not available.

7.3 Specific end use(s)
Laboratory/research use. Not for food, drug, or household use.

SECTION 8: Exposure controls / personal protection

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Occupational exposure limits: No data available.
Biological limit values: Not available.

8.2 Exposure controls
Engineering controls: Use local exhaust ventilation or other engineering controls to maintain airborne levels as low as practicable. Use enclosed handling where possible.
Personal protective equipment (PPE):
- Eye/face protection: Safety glasses with side shields or chemical splash goggles.
- Skin protection: Protective gloves (material selection dependent on use conditions). Lab coat or protective clothing.
- Respiratory protection: If ventilation is inadequate or dust is generated, use a suitable particulate respirator in accordance with applicable regulations.
- Hygiene measures: Do not eat, drink, or smoke when using this product. Wash hands after handling. Remove contaminated clothing and wash before reuse.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Test	Result
Appearance	No data available
IR spectrum	No data available
pH	No data available
Solubility	No data available

Property	Value
a) Physical State	No data available
b) Color	No data available
c) Odor	No data available
d) pH	No data available
e) Vapour Pressure	No data available
f) Viscosity	No data available
g) Initial Boiling Point and boiling range	No data available
h) Melting Point / Freezing Point	No data available
i) Auto Ignition Temperature	No data available
j) Flash Point	No data available
k) Explosion Limit, Lower	No data available
l) Explosion Limit, Upper	No data available
m) Decomposition Temperature	No data available
n) Loss on Drying	No data available
o) Relative Density	No data available
p) Solubility (in DMSO)	No data available
q) Oxidizing Properties	No data available

SECTION 10: Stability and reactivity

SECTION 10: Stability and reactivity

10.1 Reactivity
No data available.

10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
No data available.

10.4 Conditions to avoid
Avoid excessive heat. Avoid dust generation.

10.5 Incompatible materials
Not available.

10.6 Hazardous decomposition products
Not available. May emit irritating and/or toxic fumes upon thermal decomposition.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- Acute toxicity: /SIGNS AND SYMPTOMS/ Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdosage may cause nausea, and withdrawal bleeding may occur in females. For more Human Toxicity Excerpts (Complete) data for NORGESTREL (33 total), please visit the HSDB record page.
- Skin corrosion/irritation: No data available.
- Serious eye damage/eye irritation: No data available.
- Respiratory or skin sensitization: No data available.
- Germ cell mutagenicity: No data available.
- Carcinogenicity: /CASE REPORTS/ ... Presented is the case of a 45-year-old US woman with right lower quadrant pain and a 5-year history of use of a combined oral contraceptive (OC) containing 0.35 ug ethinyl estradiol and 0.35 ug norgestrel. At presentation, the uterus was enlarged to a size corresponding to 12-14 gestational weeks, with a mass at the right fundal margin. Pelvic ultrasonography revealed a large dominant leiomyoma 7.2 x 5.8 x 5.5 cm and several smaller tumors. OC use was discontinued and, 4 months later, the uterus was a size of 8-10 gestational weeks and a single serosal leiomyoma 5.9 x 4.6 x 4.4 cm remained. The leiomyoma volume had decreased by 47% after OC discontinuation, to 63 cu cm. Pelvic sonography 12 months after OC discontinuation revealed no further changes in myoma volume. In OC users with clinically significant uterine leiomyomas, discontinuation of combined OCs should be considered as a low-risk intervention with the potential to decrease uterine volume. /LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ Castrated (C3H x RIII)F1 mice ... of both sexes were fed dL-norgestrel or d-norgestrel in the diet at levels of 1 or 0.5 mg/kg, respectively. Mammary carcinomas were observed in 22/31 dL-norgestrel treated, 27/34 d-norgestrel treated and 17/29 control female mice. In the corresponding males, the incidences were 9/32, 10/32 and 10/61. The increases in incidence /for females/ were slightly raised, but the latencies of mammary tumors were unchanged.
- Reproductive toxicity: /LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ Rats were given 0.5-30 ug norgestrel orally from day 1-7 of gestation or 2 ug on days 6-8, or in a single dose /of 2 ug/ on day 6, 7 or 8. Administration of 2 ug continuously for 7 days terminated 100% of pregnancies; a single dose was effective only when given on day 6, terminating 57% of pregnancies; 2 ug given on days 6-8 terminated 50% of pregnancies. /ALTERNATIVE and IN VITRO TESTS/ The effect of synthetic progestins found in oral contraceptives has potential implications for developing embryos in women who receive oral contraceptives during early pregnancy. /Investigators/ assessed the effect of the progestin norgestrel on the developing pre-embryo. B3C6F1 mice were given 5 IU PMSG followed by 5 IU hCG 48 hr later. Studies were performed on pre-embryos recovered and pooled at both 24 hr (Group A) and 48 hr (Group B) post hCG. At each time period, they were randomly assigned to control

or norgestrel (4.0 ng/mL) treatment. In a third study, pre-embryos collected 24 hr post hCG were cultured in the absence or presence of 8.0, 80.0, or 800 ng/mL norgestrel. Cultures were performed in Ham's F-10 media with 10% fetal calf serum at 37 degrees C in an atmosphere of 5% CO2, 5% O2 and 90% N2 with 15-30 embryos per 1 mL of culture fluid. At 24 hr, 48 hr and 72 hr post recovery, cultures were viewed, the appearance of embryos noted, and number of blastomeres recorded. Compared to control groups, analysis demonstrated no significant difference in the rate of development of control and norgestrel pre-embryos in any group at any time period (24 hr, 48 hr, or 72 hr post recovery). /The authors/ conclude that norgestrel at the dose tested has no acute adverse morphological effects on development of mouse pre-embryos. This observation has potential clinical implications with regard to inadvertent use of norgestrel-containing oral contraceptives during early days of pregnancy, as well as consideration of the mechanism of action of norgestrel-containing "morning after" pills.
- STOT-single exposure: No data available.
- STOT-repeated exposure: /LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ Castrated (C3H x RIII)F1 mice ... of both sexes were fed dL-norgestrel or d-norgestrel in the diet at levels of 1 or 0.5 mg/kg, respectively. Mammary carcinomas were observed in 22/31 dL-norgestrel treated, 27/34 d-norgestrel treated and 17/29 control female mice. In the corresponding males, the incidences were 9/32, 10/32 and 10/61. The increases in incidence /for females/ were slightly raised, but the latencies of mammary tumors were unchanged.
- Aspiration hazard: No data available.

Likely routes of exposure
- /SIGNS AND SYMPTOMS/ Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdosage may cause nausea, and withdrawal bleeding may occur in females.

Symptoms related to the physical, chemical and toxicological characteristics
- /HUMAN EXPOSURE STUDIES/ The growth hormone, insulin, and blood glucose values were measured during a glucose tolerance test in 12 women before and after 3 months' use of a sequential contraceptive (11 pills containing .05 mg D-norgestrel and .05 mg ethinyl estradiol and 10 pills containing .05 mg D-norgestrel and .05 mg ethinyl estradiol). Neither fasting blood glucose nor glucose tolerance are altered during administration of the contraceptive steroids. Conversely, the reactive insulin level is significantly increased in comparison to the basal value, thus showing the signs of hyperinsulinemia. Both the gestagens and the estrogens appear to contribute to this disturbance of insulin secretion. Presumably the hyperinsulinemia is an expression of decreased sensitivity of the peripheral tissue to insulin. The growth hormone, a so-called insulin antagonist, is not responsible for the insulin resistance observed. The values measured after administration of the contraceptive do not significantly differ from the basal values.

SECTION 12: Ecological information

SECTION 12: Ecological information

12.1 Toxicity
No data available.

12.2 Persistence and degradability
No data available.

12.3 Bioaccumulative potential
No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment
Not available.

12.6 Endocrine disrupting properties
Not available.

12.7 Other adverse effects
No data available.

SECTION 13: Disposal considerations

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Dispose of contents/container in accordance with local/regional/national/international regulations. Do not discharge to drains.
Recommended disposal: Incineration or disposal via a licensed chemical waste contractor, as appropriate.
Contaminated packaging: Dispose of as unused product unless cleaned and permitted by regulations.

SECTION 14: Transport information

SECTION 14: Transport information

UN number: Not available.
UN proper shipping name: Not available.
Transport hazard class(es): Not available.
Packing group: Not available.
Environmental hazards: Not available.
Special precautions for user: Not available.
Transport in bulk according to IMO instruments: Not available.

SECTION 15: Regulatory information

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
Not available.

15.2 Chemical safety assessment
No data available.

SECTION 16: Other information

SECTION 16: Other information

Product name: Levonorgestrel Impurity 3
Catalog No.: CS-O-59188
CAS No.: 178737-52-5

Synonyms: (8R,9S,10R,13S,14S,17S)-13-ethyl-17-ethynyl-17-hydroxy-1,2,6,7,8,9,10,11,12,13,14,15,16,17-tetradecahydro-3H-cyclopenta[a]phenanthren-3-one
Parent chemical: Levonorgestrel
Supplier: Clearsynth Labs Ltd., Mumbai, India
Emergency phone: +91-22-245045900

Disclaimer: The information provided is based on available product information and is intended for guidance in safe handling. It does not constitute a guarantee of specific properties. Users are responsible for compliance with applicable laws and regulations.

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