

SAFETY DATA SHEET



Lynestrenol Formulation



Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
Date of first issue: 15.01.2016

Section 1: Identification

Product name : Lynestrenol Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Section 2: Hazard identification

GHS Classification

Germ cell mutagenicity : Category 1B

Carcinogenicity : Category 2

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure : Category 2 (Blood, Mammary gland, Uterus (including cervix), Ovary)

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H340 May cause genetic defects.
H351 Suspected of causing cancer.
H360Fd May damage fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs (Blood, Mammary gland, Uterus (including cervix), Ovary) through prolonged or repeated exposure.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.

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

Lynestrenol Formulation

Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
Date of first issue: 15.01.2016

P260 Do not breathe dust.
P281 Use personal protective equipment as required.

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 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.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch	9005-25-8	>= 10 -< 30
Lynestrenol	52-76-6	>= 1 -< 10
Talc	14807-96-6	< 10
Glycerine	56-81-5	< 10
Tocopherol	10191-41-0	< 1

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.

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 and effects, both acute and delayed : May cause genetic defects.
Suspected of causing cancer.
May damage fertility. Suspected of damaging the unborn

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.7	10.10.2020	449556-00011	Date of first issue: 15.01.2016

child.
 May cause damage to organs through prolonged or repeated exposure.
 Contact with dust can cause mechanical irritation or drying of the skin.
 Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection, 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 products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
 Use personal protective equipment.

Section 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.

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.7	10.10.2020	449556-00011	Date of first issue: 15.01.2016

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.

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 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

Section 8: Exposure controls/personal protection**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis
------------	---------	------------------------	----------------------------------	-------

SAFETY DATA SHEET



Lynestrenol Formulation



Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
 Date of first issue: 15.01.2016

		exposure)	concentration	
Starch	9005-25-8	WES-TWA	10 mg/m ³	NZ OEL
		TWA	10 mg/m ³	ACGIH
Lynestrenol	52-76-6	TWA	1 µg/m ³ (OEB 4)	Internal
		Wipe limit	10 µg/100 cm ²	Internal
Talc	14807-96-6	WES-TWA (Respirable dust)	2 mg/m ³	NZ OEL
		WES-TWA	0.1 fibres per millilitre (asbestos)	NZ OEL
<p>Further information: Confirmed carcinogen, Regulation 9(1) of the Health and Safety at Work (Asbestos) Regulations 2016 (the 'Asbestos Regulations') requires PCBUs with management or control of a workplace to ensure that exposure of a person at the workplace to airborne asbestos is eliminated so far as is reasonably practicable. If it is not reasonably practicable to eliminate exposure to airborne asbestos, exposure must be minimised so far as is reasonably practicable. Regulation 9(2) of the Asbestos Regulations requires PCBUs with management or control of a workplace to ensure that the airborne contamination standard for asbestos is not exceeded at the workplace (however, in relation to an asbestos removal area where class A asbestos removal work is being carried out, the regulations impose a more stringent standard). These requirements work together to ensure that there is a limit to the amount of asbestos that is permitted in the air of a workplace, without implying or meaning that the level delineates what is acceptable for personal exposure. Personal exposure must be eliminated or minimised so far as is reasonably practicable. The WES provided within this guide for asbestos must be applied accordingly.</p>				
		TWA (Respirable particulate matter)	2 mg/m ³	ACGIH
Glycerine	56-81-5	WES-TWA (Mist)	10 mg/m ³	NZ OEL

Engineering measures : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

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 : Combined particulates and organic vapour type

SAFETY DATA SHEET



Lynestrenol Formulation



Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
Date of first issue: 15.01.2016

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 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

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

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 : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

SAFETY DATA SHEET



Lynestrenol Formulation



Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
Date of first issue: 15.01.2016

Density : No data available

Solubility(ies)
Water solubility : No data available

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

Section 10: Stability and reactivity

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.

Section 11: Toxicological information

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Lynestrenol Formulation

Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
Date of first issue: 15.01.2016

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Lynestrenol:

Acute oral toxicity : LD50: > 1,000 - 8,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 110 mg/kg
Application Route: Intraperitoneal

Talc:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

Glycerine:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

Tocopherol:

Acute oral toxicity : LD50 (Rat): > 4,000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 3,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:**Talc:**

Species : Rabbit
Result : No skin irritation

Glycerine:

Species : Rabbit
Result : No skin irritation

Tocopherol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Starch:**

Species : Rabbit

Lynestrenol Formulation

Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
Date of first issue: 15.01.2016

Result : No eye irritation

Talc:

Species : Rabbit
Result : No eye irritation

Glycerine:

Species : Rabbit
Result : No eye irritation

Tocopherol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

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

Talc:

Exposure routes : Skin contact
Species : Humans
Result : negative

Tocopherol:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

Chronic toxicity**Germ cell mutagenicity**

May cause genetic defects.

Lynestrenol Formulation

Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
Date of first issue: 15.01.2016

Components:**Starch:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Lynestrenol:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Result: positive

Test Type: sister chromatid exchange assay
Result: positive

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow
cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive

Test Type: sister chromatid exchange assay
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive

Test Type: dominant lethal test
Species: Mouse
Application Route: Intraperitoneal
Result: positive

Germ cell mutagenicity - Assessment : Positive result(s) from in vivo somatic cell mutagenicity tests in mammals. Evidence that the substance has potential to cause mutations to germ cells

Talc:

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro
Species: Rat
Application Route: Ingestion
Result: negative

Glycerine:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.7	10.10.2020	449556-00011	Date of first issue: 15.01.2016

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Tocopherol:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity

Suspected of causing cancer.

Components:**Lynestrenol:**

Species : Mouse
Application Route : Oral
Exposure time : 80 weeks
Result : positive
Tumor Type : breast tumors, Liver
Remarks : Benign and malignant tumor(s)

Species : Rat
Application Route : Oral
Exposure time : 80 weeks
Result : positive
Tumor Type : breast tumors

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

Talc:

Species : Mouse
Application Route : inhalation (dust/mist/fume)
Exposure time : 2 Years
Result : negative

Glycerine:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Tocopherol:

Species : Rat

SAFETY DATA SHEET



Lynestrenol Formulation



Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
Date of first issue: 15.01.2016

Application Route : Ingestion
Exposure time : 104 weeks
Result : negative
Remarks : Based on data from similar materials

Reproductive toxicity

May damage fertility. Suspected of damaging the unborn child.

Components:

Lynestrenol:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat, males
Application Route: Oral
Fertility: LOAEL: 20 mg/kg body weight
Remarks: Impaired spermatogenesis

Test Type: Fertility/early embryonic development
Species: Rat, females
Application Route: Oral
Fertility: LOAEL: 375 µg/kg
Result: Maternal toxicity observed., Effects on fertility

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Oral
Fertility: LOAEL: 1,300 µg/kg
Result: Effects on fertility, Postimplantation loss.

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0.1 mg/kg body weight
Result: Effects on foetal development

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 0.1 mg/kg body weight
Result: Effects on foetal development, Postimplantation loss.

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments., Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.

Talc:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Glycerine:

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.7	10.10.2020	449556-00011	Date of first issue: 15.01.2016

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Tocopherol:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Blood, Mammary gland, Uterus (including cervix), Ovary) through prolonged or repeated exposure.

Components:**Lynestrenol:**

Target Organs : Blood, Mammary gland, Uterus (including cervix), Ovary
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Starch:**

Species : Rat
NOAEL : $\geq 2,000$ mg/kg
Application Route : Skin contact
Exposure time : 28 Days
Method : OECD Test Guideline 410

Glycerine:

Species : Rat
NOAEL : 0.167 mg/l
LOAEL : 0.622 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks

Species : Rat
NOAEL : 8,000 - 10,000 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.7	10.10.2020	449556-00011	Date of first issue: 15.01.2016

Species : Rabbit
 NOAEL : 5,040 mg/kg
 Application Route : Skin contact
 Exposure time : 45 Weeks

Tocopherol:

Species : Rat
 NOAEL : 500 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days
 Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Lynestrenol:**

Ingestion : Target Organs: Uterus (including cervix)
 Target Organs: breasts
 Target Organs: ovaries
 Target Organs: Blood
 Symptoms: Headache, Nausea, Abdominal pain, Rash, Dizziness, Tremors, Sweating, Vomiting, migraine, acne, breast tenderness, gynecomastia, menstrual irregularities, ovarian cysts
 Remarks: Used to prevent pregnancy

Section 12: Ecological information**Ecotoxicity****Components:****Talc:**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l
 Exposure time: 24 h

Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,955 mg/l
 Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10,000 mg/l
 Exposure time: 16 h
 Method: DIN 38 412 Part 8

Tocopherol:

SAFETY DATA SHEET



Lynestrenol Formulation



Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
Date of first issue: 15.01.2016

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 23.53 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility
- Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 25.8 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility
- EC50 (Pseudokirchneriella subcapitata (green algae)): > 25.8 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility
- Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 28 d
Remarks: Based on data from similar materials
- Toxicity to microorganisms : EC50: > 937 mg/l
Exposure time: 30 min
Method: ISO 8192
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Glycerine:

- Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 %
Exposure time: 30 d
Method: OECD Test Guideline 301D

Tocopherol:

- Biodegradability : Result: Not readily biodegradable.
Biodegradation: 20 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

Glycerine:

- Partition coefficient: n-octanol/water : log Pow: -1.75

SAFETY DATA SHEET



Lynestrenol Formulation



Version 3.7 Revision Date: 10.10.2020 SDS Number: 449556-00011 Date of last issue: 23.03.2020
Date of first issue: 15.01.2016

Mobility in soil

No data available

Other adverse effects

No data available

Section 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.

Section 14: Transport information

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations

NZS 5433

Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls

Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

SAFETY DATA SHEET



Lynestrenol Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.7	10.10.2020	449556-00011	Date of first issue: 15.01.2016

IECSC : not determined

Section 16: Other information

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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 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; 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

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

SAFETY DATA SHEET



Lynestrenol Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.7	10.10.2020	449556-00011	Date of first issue: 15.01.2016

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.

NZ / EN