

SAFETY DATA SHEET



Lynestrenol Formulation



Version 9.0 Revision Date: 2024/04/06 SDS Number: 449552-00019 Date of last issue: 2023/09/30
Date of first issue: 2016/01/15

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Lynestrenol Formulation

Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

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

Telephone : +1-551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : +1-215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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.

SAFETY DATA SHEET



Lynestrenol Formulation



Version 9.0 Revision Date: 2024/04/06 SDS Number: 449552-00019 Date of last issue: 2023/09/30
Date of first issue: 2016/01/15

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Important symptoms and out- : Dust contact with the eyes can lead to mechanical irritation.
lines of the emergency as- Contact with dust can cause mechanical irritation or drying of
sumed the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Starch	9005-25-8	$\geq 20 - < 30$	8-98
Lynestrenol	52-76-6	$\geq 1 - < 10$	
Talc	14807-96-6	$> 0 - < 10$	1-468
Tocopherol	10191-41-0	$\geq 0.1 - < 1$	9-864

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

SAFETY DATA SHEET



Lynestrenol Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

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

Protection of first-aiders : Dust contact with the eyes can lead to mechanical irritation.
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.

5. FIREFIGHTING 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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal pro-

SAFETY DATA SHEET



Lynestrenol Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

- gency procedures : tective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling

- 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.
- Avoidance of contact : Oxidizing agents
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

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.

Storage

- 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
- Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Threshold limit value and permissible exposure limits for each component in the work environment**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
Starch	9005-25-8	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	OEL-M (Respirable particulate matter)	1 mg/m ³	JP OEL JSOH
		OEL-M (Total particulate matter)	4 mg/m ³	JP OEL JSOH
		TWA (Respirable particulate matter)	2 mg/m ³	ACGIH

- 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.

SAFETY DATA SHEET



Lynestrenol Formulation



Version 9.0 Revision Date: 2024/04/06 SDS Number: 449552-00019 Date of last issue: 2023/09/30
Date of first issue: 2016/01/15

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
- 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.
-

9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical state : powder
- Colour : No data available
- Odour : No data available
- Odour Threshold : No data available
- Melting point/freezing point : No data available
- Boiling point, initial boiling point and boiling range : No data available
- Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
- Flammability (liquids) : No data available
- Lower explosion limit and upper explosion limit / flammability limit
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available

SAFETY DATA SHEET



Lynestrenol Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

Flash point	:	Not applicable
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	Not applicable
Auto-ignition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	Not applicable
Density and / or relative density		
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle characteristics		
Particle size	:	No data available

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.

SAFETY DATA SHEET



Lynestrenol Formulation



Version 9.0 Revision Date: 2024/04/06 SDS Number: 449552-00019 Date of last issue: 2023/09/30
Date of first issue: 2016/01/15

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : 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
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

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

Tocopherol:

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

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
Result	: No eye irritation

Talc:

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

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

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

Germ cell mutagenicity

May cause genetic defects.

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

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

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

Tocopherol:

Species	:	Rat
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.

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

Components:**Lynestrenol:**

- | | | |
|------------------------------------|---|---|
| Effects on fertility | : | <p>Test Type: Fertility/early embryonic development
 Species: Rat, males
 Application Route: Oral
 Fertility: LOAEL: 20 mg/kg body weight
 Remarks: Impaired spermatogenesis</p> <p>Test Type: Fertility/early embryonic development
 Species: Rat, females
 Application Route: Oral
 Fertility: LOAEL: 375 µg/kg
 Result: Maternal toxicity observed., Effects on fertility</p> <p>Test Type: Fertility/early embryonic development
 Species: Rabbit
 Application Route: Oral
 Fertility: LOAEL: 1,300 µg/kg
 Result: Effects on fertility, Postimplantation loss.</p> |
| Effects on foetal development | : | <p>Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: 0.1 mg/kg body weight
 Result: Effects on foetal development</p> <p>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.</p> |
| 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 | : | <p>Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Ingestion
 Result: negative</p> |
|-------------------------------|---|---|

Tocopherol:

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

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

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	:	>= 2,000 mg/kg
Application Route	:	Skin contact
Exposure time	:	28 Days
Method	:	OECD Test Guideline 410

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

Lynestrenol Formulation

Version 9.0	Revision Date: 2024/04/06	SDS Number: 449552-00019	Date of last issue: 2023/09/30 Date of first issue: 2016/01/15
----------------	------------------------------	-----------------------------	---



Remarks: Used to prevent pregnancy

12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Talc:**

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

Tocopherol:

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:****Tocopherol:**

Biodegradability	: Result: Not readily biodegradable.
------------------	--------------------------------------

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

Biodegradation: 20 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301F

Bioaccumulative potential

No data available

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
 Do not dispose of waste into sewer.

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.

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : Not applicable
 Proper shipping name : Not applicable
 Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
 Proper shipping name : Not applicable
 Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 Packing instruction (cargo aircraft) : Not applicable
 Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
 Proper shipping name : Not applicable

SAFETY DATA SHEET



Lynestrenol Formulation



Version 9.0 Revision Date: 2024/04/06 SDS Number: 449552-00019 Date of last issue: 2023/09/30
Date of first issue: 2016/01/15

Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Talc (Mg ₃ H ₂ (SiO ₃) ₄) (without asbestos and quartz)	>0 - <10	From April 1st, 2025

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

SAFETY DATA SHEET



Lynestrenol Formulation



Version 9.0 Revision Date: 2024/04/06 SDS Number: 449552-00019 Date of last issue: 2023/09/30
Date of first issue: 2016/01/15

Chemical name	Remarks
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	From April 1st, 2025

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
 JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
 JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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; KECl - 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, Bioaccumu-

SAFETY DATA SHEET



Lynestrenol Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2024/04/06	449552-00019	Date of first issue: 2016/01/15

lative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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 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.

JP / EN