

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Lynestrenol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	06.04.2024	9372565-00007	Date of first issue: 27.08.2021

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

1.1 Product identifier

Trade name : Lynestrenol Formulation

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

Use of the Sub-
stance/Mixture : Pharmaceutical

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone : +44 1 670 59 32 05

E-mail address of person
responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

+1-215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Germ cell mutagenicity, Category 1B
Carcinogenicity, Category 2
Reproductive toxicity, Category 1A

Specific target organ toxicity - repeated
exposure, Category 2

H340: May cause genetic defects.
H351: Suspected of causing cancer.
H360Fd: May damage fertility. Suspected of dam-
aging the unborn child.
H373: May cause damage to organs through pro-
longed or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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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 through prolonged or repeated exposure.
Precautionary statements	:	Prevention: P201 Obtain special instructions before use. 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.

Hazardous components which must be listed on the label:

Lynestrenol
EUH208 Contains Tocopherol. May produce an allergic reaction.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Lynestrenol	52-76-6 200-151-4	Acute Tox. 4; H302 Muta. 1B; H340 Carc. 2; H351	>= 1 - < 10

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		Repr. 1A; H360Fd STOT RE 1; H372 (Blood, Mammary gland, Uterus (in- cluding cervix), Ovary)	
Tocopherol	10191-41-0 233-466-0	Skin Sens. 1B; H317	$\geq 0.1 - < 1$
Substances with a workplace exposure limit :			
Starch	9005-25-8 232-679-6		$\geq 20 - < 30$
Talc	14807-96-6 238-877-9		$\geq 1 - < 10$
Glycerine	56-81-5 200-289-5		$\geq 1 - < 10$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : May cause genetic defects.
Suspected of causing cancer.

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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.
Dust contact with the eyes can lead to mechanical irritation.

May produce an allergic reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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

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Hygiene measures : 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.
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

dust of any kind 10 mg/m³
Value type (Form of exposure): TWA (Inhalable)
Basis: GB EH40

4 mg/m³
Value type (Form of exposure): TWA (Respirable fraction)
Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Starch	9005-25-8	TWA (inhalable dust)	10 mg/m ³	GB EH40
		TWA (Respirable)	4 mg/m ³	GB EH40

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Lynestrenol	52-76-6	dust) TWA	1 µg/m3 (OEB 4)	Internal
		Wipe limit	10 µg/100 cm ²	Internal
Talc	14807-96-6	TWA (Respirable dust)	1 mg/m3	GB EH40
Glycerine	56-81-5	TWA (Mist)	10 mg/m3	GB EH40

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Glycerine	Workers	Inhalation	Long-term local effects	56 mg/m3
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m3
Tocopherol	Workers	Inhalation		44 mg/m3
	Workers	Skin contact		125 mg/kg bw/day
	Consumers	Inhalation		10.8 mg/m3
	Consumers	Skin contact		62.5 mg/kg bw/day
	Consumers	Ingestion		6.25 mg/kg bw/day

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Glycerine	Fresh water	0.885 mg/l
	Marine water	0.0885 mg/l
	Intermittent use/release	8.85 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	3.3 mg/kg dry weight (d.w.)
	Marine sediment	0.33 mg/kg dry weight (d.w.)
	Soil	0.141 mg/kg dry weight (d.w.)

8.2 Exposure controls

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

Eye/face protection : Wear safety glasses with side shields or goggles.

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Hand protection		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.
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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.
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

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Relative density	:	No data available
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.

9.2 Other information

Flammability (liquids)	:	No data available
Particle size	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
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10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
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10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

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:

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

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

Starch:

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

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

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

Skin corrosion/irritation

Not classified based on available information.

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Components:

Tocopherol:

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

Talc:

Species : Rabbit
Result : No skin irritation

Glycerine:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Tocopherol:

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

Starch:

Species : Rabbit
Result : No eye irritation

Talc:

Species : Rabbit
Result : No eye irritation

Glycerine:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Tocopherol:

Test Type : Local lymph node assay (LLNA)

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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

Starch:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Talc:

Exposure routes : Skin contact
Species : Humans
Result : negative

Germ cell mutagenicity

May cause genetic defects.

Components:

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

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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

Starch:

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

Talc:

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA syn-
thesis 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

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

Carcinogenicity

Suspected of causing cancer.

Components:

Lynestrenol:

Species : Mouse
Application Route : Oral
Exposure time : 80 weeks

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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

Tocopherol:

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

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

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

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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.

Tocopherol:

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

Talc:

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

Glycerine:

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

STOT - single exposure

Not classified based on available information.

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STOT - repeated exposure

May cause damage to organs 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:

Tocopherol:

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

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

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

Aspiration toxicity

Not classified based on available information.

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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

12.1 Toxicity

Components:

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 microorganisms : EC50 : > 937 mg/l
Exposure time: 30 min
Method: ISO 8192
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC: > 100 mg/l
Exposure time: 28 d
Species: Oncorhynchus mykiss (rainbow trout)
Remarks: Based on data from similar materials

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

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

12.2 Persistence and degradability

Components:

Tocopherol:

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

Glycerine:

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

12.3 Bioaccumulative potential

Components:

Glycerine:

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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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12.6 Other adverse effects

Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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.

SECTION 14: Transport information

14.1 UN number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

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ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Not applicable
Control of Major Accident Hazards Regulations 2015 (COMAH)	:	Not applicable

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS	:	not determined
DSL	:	not determined

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IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H340 : May cause genetic defects.
H351 : Suspected of causing cancer.
H360Fd : May damage fertility. Suspected of damaging the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Carc. : Carcinogenicity
Muta. : Germ cell mutagenicity
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Ef-

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fect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Classification of the mixture:

Muta. 1B	H340
Carc. 2	H351
Repr. 1A	H360Fd
STOT RE 2	H373

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

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.

GB / EN