Norethisterone (Norethindrone)

Version number: 1

Issued: 2023-12-22



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

1.1. Product identifier

Trade name

Norethisterone (Norethindrone)

CAS number

68-22-4

EC number

200-681-6

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

Research and development.

Not suitable for use in

Not suitable for human consumption or veterinary purposes.

1.3. Details of the supplier of the safety data sheet

Supplier

Molekula Group

Address

Molekula Ltd, Lingfield Way, Darlington, DL1 4XX Darlington United Kingdom

Telephone

+44 (0) 3302 000 333

Email

info@molekula.com

Web site

www.molekula.com

Contact person

Kevin Banks

<u>Email</u>

+44 (0) 7769276927

1.4. Emergency telephone number

Poison center/Additional emergency number

0344 892 0111 - National Poisons Information Service (Newcastle Centre)

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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Classification

Carcinogenicity, hazard category 2

Hazardous to the aquatic environment — Acute hazard category 1

Hazardous to the aquatic environment — Chronic hazard category 1

Reproductive toxicity, hazard category 1A

Reproductive toxicity, Effects on or via lactation, additional hazard category

Hazard statements

H351, H360, H362, H400, H410

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms





Signal word

Danger

Hazard statements

H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

H362 May cause harm to breast-fed children.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P201 Obtain special instructions before use.

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

P260 Do not breathe dust/fumes/gas/mist/vapours/spray.

P263 Avoid contact during pregnancy and while nursing.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P391 Collect spillage.

P308 + P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container to local regulations.

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2.3. Other hazards

No data available

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical name	CAS No. EC No. REACH No. Index No.	Concentration	Classification	H-phrase M factor acute M factor chronic	Note
Norethisterone (Norethindrone)	68-22-4 200-681-6 -	100%	Carc. 2, Repr. 1A, Lact., Aquatic Acute 1, Aquatic Chronic 1	H351, H360FD, H362, H400, H410 -	-

Molecular weight

298.19

Substance additional information

For the complete text of H- / EUH-statements mentioned in this section, see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Get medical attention if any discomfort continues. Show this Safety Data Sheet (SDS) to medical personnel.

Inhalation

IF INHALED: Remove person to fresh air and keep comfortable for breathing. In case of persistent throat irritation or coughing: Seek medical attention and bring these instructions.

Skin contact

IF ON SKIN: Wash with plenty of water. Continue to rinse for at least 15 minutes and seek medical attention. Get medical advice/attention if you feel unwell.

Eye contact

Remove contact lenses if present. Rinse eyes with water. Continue to rinse for at least 15 minutes and seek medical attention.

Ingestion

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

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Information for doctors

First aiders/ medical personnel need to protect themselves.

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

The severity of the symptoms described will vary dependant of the concentration and the length of exposure.

Inhalation

Single exposure may cause the following adverse effects: Upper respiratory irritation. Difficulty in breathing.

Skin contact

Single exposure may cause the following adverse effects: Severe skin irritation.

Eye contact

Single exposure may cause the following adverse effects: Severe irritation.

Ingestion

Single exposure may cause the following adverse effects: Severe abdominal pain. Nausea, vomiting.

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

Treat symptomatically. No special treatment requirement.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

In case of fire: Use foam, carbon dioxide, dry powder or water fog to extinguish.

Unsuitable extinguishing media

No specific fire fighting procedure given.

5.2. Special hazards arising from the substance or mixture

Specific hazards: Combustible.

Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

Carbon dioxide (CO2). Carbon monoxide (CO).

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters

Evacuate area. Avoid breathing gas, fume, vapours or spray. Cool containers exposed to heat with water spray and remove container, if no risk is involved.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid breathing dust/fume/gas/mist/vapours/spray. Provide adequate ventilation. Avoid contact with skin and eyes. For personal protection, see section 8.

6.2. Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Collect spillage with shovel, broom or the like and reuse, if possible. Dispose of large amounts of spillage/waste according to agreement with local authorities.

6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Preventive handling precautions

For precautions see section 2.2. Wear protective clothing, gloves, eye and face protection. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid ingestion and inhalation. Work under hood

General hygiene

Observe good chemical hygiene practices. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove contaminated clothing and launder thoroughly before re-use. Wash skin thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Store at ambient temperature. Store in a dry place. Store in a closed container.

7.3. Specific end use(s)

No specific usage precautions noted.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available

8.2. Exposure controls

Personal Protective Equipment Symbols











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Eye / face protection

Wear eye protection.

Hand protection

Wear protective gloves. Recommended gloves: Nitrile.

Glove Thickness: 0.11mm Breakthrough time: 8 hours

Always inspect gloves before use. If signs of wear and tear are noticed then the gloves should be replaced.

No specific hygiene procedures noted, but good personal hygiene practices are always advisable, especially when working with chemicals. Wash contaminated skin thoroughly after handling.

Other skin protection

Wash skin thoroughly after handling.

Respiratory protection

Provide adequate ventilation. If ventilation is insufficient, suitable respiratory protection must be provided.

Environmental exposure controls

Avoid discharge into drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

Solid

<u>Colour</u>

No data available

<u>Odour</u>

No data available

Melting point / freezing point

205 - 206 °C

Boiling point or initial boiling point and boiling range

No data available

Flammability

No data available

Lower and upper explosion limit

No data available

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Flash point

No data available

Auto-ignition temperature

No data available

Decomposition temperature

No data available

<u>рН</u>

No data available

Kinematic viscosity

No data available

Solubility

No data available

Water solubility

0.0056 g/l at 25 °C

Partition coefficient n-octanol/water

log Pow: 2.7 at 25 °C

Vapour pressure

< 0.1 hPa at 25 °C

Density and/or relative density

1.19 at 20 °C

Relative vapour density

No data available

Particle characteristics

No data available

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

There are no known reactivity hazards associated with this product.

10.2. Chemical stability

Stable under the prescribed storage conditions.

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10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

Strong oxidising agents.

10.6. Hazardous decomposition products

See section 5.

SECTION 11: Toxicological information

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

Product / Substance name CAS / EC no.	Dose descriptor	Value / Dose	Exposure route	Test animals
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	LD50	6000 mg/kg	Oral	Mouse

Skin corrosion/irritation

Product / Substance name CAS / EC no.	Result	Duration of exposure	Species
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	No skin irritation.	20 minutes	reconstructed human epi- dermis (RhE)
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	No skin irritation.	3-60 minutes	reconstructed human epi- dermis (RhE)

Serious eye damage/irritation

Product / Substance name CAS / EC no.	Result	Duration of exposure	Species
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	No eye irritation.	5 minutes	Chicken eye

Germ cell mutagenicity

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Product / Substance name CAS / EC no.	Result	Metabolic activation / Exposure	Species	Method / Guideline
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	Negative.	with and without meta- bolic activation	Chinese hamster lung cells	In vitro mammalian cell gene mutation test.

Carcinogenicity

Product / Substance name CAS / EC no.	Other
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	Suspected of causing cancer.

Reproductive toxicity

Product / Substance name CAS / EC no.	Result
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	May damage the unborn child. Positive evidence from human epidemiological studies.
	Reproductive toxicity (Lactation): May damage fertility. Positive evidence from human epidemiological studies.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

Acute fish toxicity

Product / Substance name CAS / EC no.	Measurement type	Value / Result	Duration of exposure	Species
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	LC50	>5.028 mg/l	96 hours	Brachydanio rerio (Zebra Fish)

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Acute algae toxicity

Product / Substance name CAS / EC no.	Measurement type	Value / Result	Duration of exposure	Species
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	NOEC	0.013 mg/l	72 hours	Desmodesmus sub- spicatus (green algae)
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	ErC50	0.51 mg/l	72 hours	Desmodesmus sub- spicatus (green algae)

Acute crustacean toxicity

Product / Substance name CAS / EC no.	Measurement type	Value / Result	Duration of exposure	Species
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	EC50	>4.6 mg/l	48 hours	Daphnia magna

Micro-/macro organism toxicity

Product / Substance name CAS / EC no.	Measurement type	Value / Result	Duration of exposure	Species
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	EC10	>7.8 mg/l	16 hours	Pseudomonas putida

12.2. Persistence and degradability <u>Persistence and degradability</u>

Product / Substance name CAS / EC no.	Type of test	Result	Degradation
Norethisterone (Norethindrone) 68-22-4 / 200-681-6	aerobic	0%	The product is not readily biodegradable.

12.3. Bioaccumulative potential

No data available

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12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Endocrine disrupting properties

This product does not contain any known or suspected endocrine disruptors.

12.7. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal considerations

Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

14.1. UN number

3077

14.2. UN proper shipping name

ADR / RID / ADN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Norethisterone)

IMDG proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Norethisterone)

IATA proper shipping name

Environmentally hazardous substance, solid, n.o.s. (Norethisterone)

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14.3. Transport hazard class(es)

<u>Label</u>

ADR/RID/ADN





9

Environmental hazard

IMDG





9

Environmental hazard

IATA





9

Environmental hazard

ADR / RID Class

a

ADR / RID Classification code

M7

ADR / RID hazard identification number

٩n

IMDG Class

9

IATA Class

9

ADN Class

9

ADN Class Code

M7

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14.4. Packing group

ADR / RID / ADN: III

IMDG: III IATA: III

14.5. Environmental hazards

ADR/RID/ADN: Hazardous for the environment

IMDG EmS

F-A, S-F

14.6. Special precautions for user

Tunnel restriction code: - Transport category: 3

14.7. Maritime transport in bulk according to IMO instruments

IBC Instruction: IBC08

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture <u>EU regulations</u>

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006. This material safety data sheet complies with the requirements of Regulation (EU) 2020/878.

National regulations

No data available

15.2. Chemical safety assessment

No data available

SECTION 16: Other information

Phrase meaning

Carc. 2 - Carcinogenicity, hazard category 2

Aquatic Acute 1 - Hazardous to the aquatic environment — Acute hazard category 1

Aquatic Chronic 1 - Hazardous to the aquatic environment — Chronic hazard category 1

Repr. 1A - Reproductive toxicity, hazard category 1A

Lact. - Reproductive toxicity, Effects on or via lactation, additional hazard category

H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

H360FD May damage fertility. May damage the unborn child

H362 May cause harm to breast-fed children.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.