



SAFETY DATA SHEET
REACH regulation (EC) n° 1907/2006 - n°2020/878

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : Trilorale 50mg/ml

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

General Use : veterinary specialty

Use : For professional

1.3. Details of the supplier of the safety data sheet

Registered company name AXIENCE SAS

Address : 14 r Scandicci, 93500 Pantin

Telephone : +33(0)1 41 83 23 10

Mail box : contact@axience.fr

Web site : www.axience.fr

1.4. Emergency telephone number

Company/Organization : INRS / ORFILA <http://www.centres-antipoison.net>

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Reproductive toxicity, Category 2 (Repr. 2, H361)

This mixture is not classified for physical hazard.

This mixture is not classified for environmental hazard.

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments

Hazard pictograms :



Signal Word :

WARNING

Product identifiers :

Trilostane

Additional labeling :

EUH 205 Contains epoxy constituents. May produce an allergic reaction.

Hazard statements :

H361 Suspected of damaging fertility or the unborn child.

Precautionary statements

P201 Obtain special instructions before use.

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

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

2.3. Other hazards

The mixture does not contain substances classified as "Substances of Very High Concern" (SVHC) $\geq 0,1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006

The mixture does not contain substances $\geq 0.1\%$ with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or in Regulation (EU) 2018/605 of the Commission.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**3.1. Substances****3.2. Mixtures****Composition :**

Identification	(EC) 1272/2008	Rating (VLE / CMF)	%
CAS: 13647-35-3	Skin Irrit. 2, H315	[2]	3 - 5
CE: 237-133-0	Eye irrit. 2, H319		
Trilostane	Repr.2, H361		

(Full text of H-phrases: see section 16)

Information on ingredients :

[2] CMR substance

SECTION 4: FIRST AID MEASURES

In general, in case of doubt or if symptoms persist, always call a doctor. Never give anything by mouth to an unconscious person.

4.1. Description of first aid measures**- In case of inhalation :**

Breathe fresh air and keep warm and at rest.

If breathing is irregular or stopped, practice artificial respiration and call a doctor.

In the event of contact with eyes :

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of contact with skin :

Take off contaminated clothing.

Beware of the product that can remain between the skin and clothing, watch, shoes,...

Wash skin immediately with soap and water. Rinse thoroughly.

In case of redness, consult a doctor.

In the event of swallowing :

Rinse mouth.

Nothing to do

Keep the person exposed at rest. Do not force vomiting

Seek medical attention immediately, showing the label

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

No data available.

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

No data available.

SECTION 5: FIREFIGHTING MEASURES

Product not labeled flammable.

5.1. Extinguishing media

Suitable methods of extinction

In the event of a fire, use :

- In the event of a fire, use a suitable fire extinguisher depending on the origin of the fire.

Unsuitable methods of extinction

In the event of a fire, do not use :

- water jet

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke

In case of fire, may form :

- carbon monoxide (CO)

- carbon dioxide (CO₂)

5.3. Advice for firefighters

Use a self-contained breathing apparatus and a full protective suit.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

Consult the safety measures listed under heading 7 and 8

Ensure proper ventilation.

Use personal protective equipment.

For non-emergency personnel :

Avoid any contact with the skin and eyes

Wear recommended personal protective equipment.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (see section 8)

6.2. Environmental precautions

leaks or spills with non-diatomaceous earth in

Prevent any material from entering drains or waterways

6.3. Methods and material for containment and cleaning up

If the soil is soiled, and after recovery of the product by wiping it with an inert absorbent material and not combustible, wash the surface that has been soiled with plenty of water.

Clean preferably with a detergent, do not use solvents

6.4. Reference to other sections

Refer to section 7 - Handling and storage

Refer to section 8 - Exposure Controls and Personal Protection

Refer to section 13 - Disposal considerations

SECTION 7: HANDLING AND STORAGE**7.1. Precautions for safe handling**

Use the required personal protective equipment.

Wash your hands after every use.

Remove and wash contaminated clothing before use.

Close the cap securely after use.

Ensure proper ventilation.

Fire prevention

Prevent access by unauthorised personnel

Handle in well ventilated areas.

Recommended equipment and procedures :

For personal protection, see section 8

Observe precautions stated on label and also industrial safety regulations.

Wash contaminated clothing before reuse.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used

7.2. Conditions for safe storage, including any incompatibilities

Keep containers closed out of use.

Keep away from food and drink, including animal feeds and drinks

Store away from frost and heat.

Store in the original container.

7.3. Specific end use(s)

For professional use.

Please refer to paragraph 1 concerning the use of the product

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters****Occupational exposure limits :**

- France (INRS - ED984 :2016)

This product does not contain any substance with exposure limits.

Derived no effect level (DNEL) or derived minimum effect level (DMEL):

Not relevant

8.2. Exposure controls**Personal protection measures, such as a personal protective equipment**

Use personal protective equipment that is clean and has been properly maintained

Store personal protective equipment in a clean place, away from the work area

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

Ensure relevant ventilation of the workstation.

Eye/face protection

Avoid contact with eyes

Before any handling, it is necessary to wear side protection goggles complying with standard NF EN166.

In case of increased danger, use a face shield for face protection.

Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

Hand protection

Use appropriate protective gloves resistant to chemical agents in accordance with standard NF EN374.

The selection of gloves should be made according to the application and the duration of use at the workstation.

Protective gloves must be chosen according to the workstation: other chemicals that can be handled, physical protection required (cuts, pricks, thermal protection), dexterity required.

- Body protection

Wear suitable protective clothes.

Staff will wear regularly washed work clothing.

After contact with the product, all soiled parts of the body should be washed.

Respiratory protection

Not concerned in the conditions of employment

In case of insufficient ventilation, wear appropriate breathing apparatus. Mask with P3 filter.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties****General information**

Physical state :	Liquid
Color :	Colorless
Odour :	without

Important health, safety and environmental information

Melting point/freezing point :	Not relevant
Boiling point or initial boiling point and boiling range :	Not relevant
Flammability :	Not relevant
Lower and upper explosion limit :	Not relevant
Flash point :	Not relevant
Auto-ignition temperature :	Not relevant
Decomposition temperature :	Not relevant
pH :	Not relevant
Kinematic viscosity :	Not relevant
Solubility :	Not relevant
Partition coefficient n-octanol/water (log value) :	Not relevant
Vapour pressure :	Not relevant
Density and/or relative density :	Not relevant
Relative vapour density :	Not relevant
Particle characteristics :	Not relevant

9.2. Other information

No data available

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

The mixture is stable under handling and storage normal conditions.

10.2. Chemical stability

The mixture is stable under the recommended handling and storage conditions in section 7

10.3. Possibility of hazardous reactions

None known in the present state of our knowledge

10.4. Conditions to avoid

Avoid :

- frost
- heat

10.5. Incompatible materials

Do not mix with other products

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO₂)

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****11.1.1. Substances**

Trilostane (CAS: 13647-35-3)

Oral route : DL50 = > 15000 mg/kg

Species : Rat

11.1.2. Mixtures**Acute toxicity :**

On the basis of the available data, classification criteria are not reached

Skin corrosion/skin irritation :

On the basis of the available data, classification criteria are not reached

Serious damage to eyes/eye irritation :

On the basis of the available data, classification criteria are not reached

Respiratory or skin sensitisation :

On the basis of the available data, classification criteria are not reached

Germ cell mutagenicity :

On the basis of the available data, classification criteria are not reached

Carcinogenicity :

On the basis of the available data, classification criteria are not reached

Reproductive toxicant :

Suspected of damaging fertility or the unborn child.

Specific target organ systemic toxicity- single exposure :

On the basis of the available data, classification criteria are not reached

Specific target organ systemic toxicity- repeated exposure :

On the basis of the available data, classification criteria are not reached

Aspiration hazardous :

On the basis of the available data, classification criteria are not reached

11.2. Information on other hazards**11.2.1 Properties disrupting the endocrine system**

No data available

11.2.2. Other information

No data available

SECTION 12: ECOLOGICAL INFORMATION

Do not dispose of residues in sewers and waterways.

12.1. Toxicity

The mixture is not classified dangerous for environment in accordance with the CLP1272/2008 rules.

12.1.1. Substances

Not relevant

12.1.2. Mixtures**12.2. Persistence and degradability****12.2.1 Substances**

Trilostane (CAS: 13647-35-3)

Biodegradability : Non-rapidly degradable.

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6 Properties disrupting the endocrine system

No data available

12.7. Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC

13.1. Waste treatment methods

Do not pour into drains or waterways

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container

Give a certified disposal contractor

Codes of wastes (Decision 2014/955/EC, Directive 2008/98/EEC on hazardous waste) :

No information.

SECTION 14: TRANSPORT INFORMATION

Exempt from transport classification and labelling.

14.1. UN number or ID number

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

14.4. Packing group

-

14.5. Environmental hazards

-

14.6. Special precautions for user

-

14.7. Maritime transport in bulk according to IMO instruments

-

SECTION 15: REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****- Classification and labelling information included in section 2**

The following regulations have been used :

- Regulation (EC) n°1272/2008 and adaptations

- Container information :**- Particular provisions :**

No data available

- Labelling of detergent (Regulation (EC) No 648/2004 and 907/2006) :

Not concerned

15.2. Chemical safety assessment

The chemical safety assessment is carried out for the substances concerned. The data is indicated in the different sections of the safety data sheet.

SECTION 16: OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions

It is all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof

The following regulations have been used according to regulation (EC) No. 1272/2008 and its amendments.

Wording of the phrases mentioned in section 3 :

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H361	Suspected of damaging fertility or the unborn child <state specific effect if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

Abbreviations :

DNEL : Derived No-Effect Level

PNEC : Predicted No-Effect Concentration

ADR : European agreement concerning the international carriage of dangerous goods by Roads

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

PBT : Persistent, bioaccumulable and toxic

STP: wastewater treatment plant

TMP: table of occupational diseases

vPvB : Very persistent, very bioaccumulable

SVHC: Substance of Very High Concern

IMO : International Maritime Organization