

Section 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier

Product Name: ORASO®
Product Code: 073-01

Unique Formula Identifier (UFI) 7Q07-03G0-5207-2FRS

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

Product Use: Fungicide

1.3 Details of the supplier of the safety data sheet

Company: Life Scientific Ltd,
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Belfield Office Park,
Beech Hill Road,
Dublin 4
Ireland
Telephone: +353 (0) 1 2832024
Email: info@lifescientific.com
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1.4 Emergency contact information

In case of Emergency: Tel. NPIC +353 (01) 809 2166 (8.00 a.m. to 10.00 p.m. - Public)
Tel. NPIC +353 (01) 809 2566 (Healthcare Professionals)

Section 2. HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EU) No. 1272/2008

Skin irritation	Category 2	H315
Skin Sensitisation	Category 1	H317
Eye irritation	Category 2	H319
STOT SE	Category 3	H335
Reproductive toxicity	Category 2	H361d
Acute aquatic	Category 1	H400
Aquatic Chronic	Category 1	H410

2.2 Label Elements

Labelling according to Regulation (EU) 1272/2008

Hazard components which must be listed on the label:

- Tebuconazole
- Prothioconazole
- N,N-Dimethyl decanamide

Hazard Pictograms:



Signal Word:

Warning

Hazard Phrases:

H315 Causes skin irritation.
H317 May cause an allergic skin reaction
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H361d Suspected of damaging the unborn child.
H410 Very toxic to aquatic life with long lasting effects

Precautionary Phrases:

P102 Keep out of reach of children
P264 Wash hands thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P261 Avoid breathing spray.
P308 +P313 If exposed or concerned: Get medical advice/attention.
P391 Collect spillage
P501 Dispose of contents/container to a licensed hazardous waste disposal contractor or collection site except for triple-rinsed empty containers which can be disposed of as non-hazardous waste.

Other Phrases:

EUH401 To avoid risks to human health and the environment, comply with the instructions for use.
EUH208 Contains 2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-phenylpropyl]-2,4-dihydro-3H-1,2,4- triazole-3-thione. May produce an allergic reaction.

2.3 Other Hazards

No other hazards known.

Section 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

No substances fulfil the criteria set out in Annex II, Part A of the REACH Regulation (EC) No 1907/2006.

3.2 Mixtures

Chemical Name	CAS	EC	Classification (Regulation (EC) No 1272/2008)	Concentration (% w/w)
Prothioconazole	178928-70-6	-	Aqua. Acute 1, H400 Aquatic Chronic 1, H410	12.76
Tebuconazole	107534-96-3	403-640-2	Acute Tox 4, H302 Aquatic Acute 1 H400 Repr. 2, H361d Aquatic Chronic 1, H410	12.76
N,N-Dimethyl decanamide	14433-76-2	238-405-1	Skin Irrit 2 H315 Eye Irrit 2 H319 STOT SE 3 H335 Aquatic Chronic 3 H412	>20

Further information

Prothioconazole	178928-70-6	M-Factor: 10 (Acute)
Tebuconazole	107534-96-3	M-Factor: 1 (Acute), 10 (chronic)

Section 4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice	Move out of dangerous area. Place and transport victim in stable position (lying sideways). Remove contaminated clothing immediately and dispose of safely.
Inhalation	Move to fresh air. Keep patient warm and at rest. Call a physician or poison control center immediately.
Skin contact	Wash off thoroughly with plenty of soap and water, if available with polyethyleneglycol 400, subsequently rinse with water. If symptoms persist, call a physician.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Do NOT induce vomiting. Call a physician or poison control center immediately.

4.2 Most important symptoms and effects, both acute and delayed

No known symptoms

4.3 Indication of any immediate medical attention and special treatment needed

Information to physician: Treat symptomatically. In case of ingestion gastric lavage should be considered in cases of significant ingestions only within the first 2 hours. However, the application of activated charcoal and sodium sulphate is always advisable. There is no specific antidote.

Section 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable: High volume water jet

5.2 Special hazards arising from the substance or mixture

In the event of fire the following may be released: Hydrogen chloride (HCl), Hydrogen cyanide (hydrocyanic acid), Carbon monoxide (CO), Sulphur oxides, Nitrogen oxides (NOx).

5.3 Advice for firefighters

In the event of fire and/or explosion do not breathe fumes. Wear self-contained breathing apparatus and protective suit.
Further information
Contain the spread of the fire-fighting media. Do not allow run-off from firefighting to enter drains or water courses.

Section 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with spilled product or contaminated surfaces. Use personal protective equipment

6.2 Environmental precautions

Do not allow to get into surface water, drains and ground water. If the product contaminates rivers and lakes or drains inform respective authorities

6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Clean contaminated floors and objects thoroughly, observing environmental regulations. Collect and transfer the product into a properly labelled and tightly closed container.

6.4 Reference to other sections

Information regarding safe handling, see section 7. Information regarding personal protective equipment, see section 8. Information regarding waste disposal, see section 13

Section 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Hygiene measures: Avoid contact with skin, eyes and clothing. Keep working clothes separately. Wash hands before breaks and immediately after handling the product. Remove soiled clothing immediately and clean thoroughly before using again. Garments that cannot be cleaned must be destroyed (burnt).

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Store in a place accessible by authorized persons only. Protect from freezing. Keep away from direct sunlight.

Advice on common storage: Keep away from food, drink and animal feeding stuffs.

7.3 Specific end use(s)

Refer to the label and/or leaflet.

Section 8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 Control parameters

Component	CAS-No.	Control parameters
Prothioconazole	178928-70-6	1.4 mg/m ³
Tebuconazole	07534-96-3	0.2 mg/m ³

8.2 Exposure controls

Personal protective equipment:
In normal use and handling conditions please refer to the label and/or leaflet. In all other cases the following recommendations would apply.

Respiratory protection: Wear respirator with a particle filter mask (protection factor 4) conforming to European norm EN149FFP1 or equivalent. Respiratory protection should only be used to control residual risk of short duration activities, when all reasonably practicable steps have been taken to reduce exposure at source e.g. containment and/or local extract ventilation. Always follow respirator manufacturer's instructions regarding wearing and maintenance

Skin protection: Wear standard coveralls and Category 3 Type 6 suit. If there is a risk of significant exposure, consider a higher protective type suit. Wear two layers of clothing wherever possible. Polyester/cotton or cotton overalls should be worn under chemical protection suit and should be professionally laundered frequently. If chemical protection suit is splashed, sprayed or significantly contaminated, decontaminate as far as possible, then carefully remove and dispose of as advised by manufacturer.

Hand protection: Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. Wash gloves when contaminated. Dispose of when contaminated

inside, when perforated or when contamination on the outside cannot be removed.
Wash hands frequently and always before eating, drinking, smoking or using the toilet.
Protective gloves complying with EN 374.

Eye protection: Wear goggles (conforming to EN166, Field of Use = 5 or equivalent).

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Liquid.
Colour:	Clear pale yellow to slightly turbid brown liquid
Odour:	Aromatic
Melting point (°C):	140.3 °C Prothioconazole 105 °C Tebuconazole
Freezing point (°C):	No data available
Boiling point (°C):	No data available
Lower and upper exp. Limit:	No data available
Flash Point:	> 148 °C
Auto. Ignition temp (°C):	No data available
Decomposition temp (°C):	No data available
pH (at 20 °C):	5 - 7 at (1%) (20°C)
Dynamic viscosity:	49.9 mPa.s (20 °C)
Solubility:	Emulsifiable.
Part. Coef. m-octanol/water:	Prothioconazole: log Pow: 3.82 (20 °C) (pH 7) Tebuconazole: log Pow: 3.7 N,N-Dimethyldecanamide: log Pow: 2.46
Vapour pressure:	No data available
Density:	ca. 0.98 g/cm ³ (20 °C)
Relative vapour density:	No data available
Particle characteristics:	No data available

9.2 Other Information

9.2.1 Information with regard to physical hazard classes

Explosives:	Not Explosive.
Oxidizing properties:	No oxidizing properties
Flammable liquids:	Non-flammable.
Surface tension:	ca. 29.1 mN/m (20 °C)

9.2.2 Other safety characteristics

Further safety related physical-chemical data are not known.

Section 10. STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical Stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions when stored and handled according to prescribed instructions

10.4 Conditions to avoid

Extremes of temperature and direct sunlight.

10.5 Incompatible material

Store only in the original container.

10.6 Hazardous decomposition products

No decomposition products expected under normal conditions of use.

Section 11. TOXICOLOGICAL INFORMATION

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

Acute oral toxicity:	LD50 (Rat) > 2,500 mg/kg (Similar product)
Acute inhalation toxicity:	LC50 (Rat) > 5.153 mg/l (Similar product) Exposure time: 4 h Irritating to respiratory system.
Acute dermal toxicity:	LD50 (Rat) > 4,000 mg/kg (Similar product)
Skin corrosion/irritation:	Irritating to skin. (Rabbit)
Serious eye damage/eye irritation:	Irritating to eyes. (Rabbit)
Respiratory or skin sensitisation:	Skin: Non-sensitizing. (Guinea pig) OECD Test Guideline 406

Assessment repeated dose toxicity

Prothioconazole did not cause specific target organ toxicity in experimental animal studies.

Tebuconazole did not cause specific target organ toxicity in experimental animal studies.

N,N-Dimethyldecanamide did not cause specific target organ toxicity in experimental animal studies.

Based on a similar formulation.

Assessment mutagenicity

Prothioconazole was not mutagenic or genotoxic based on the overall weight of evidence in a battery of in vitro and in vivo tests.

Tebuconazole was not mutagenic or genotoxic in a battery of in vitro and in vivo tests.

N,N-Dimethyldecanamide was not genotoxic in a battery of in vitro tests.

Based on a similar formulation.

Assessment carcinogenicity

Prothioconazole was not carcinogenic in lifetime feeding studies in rats and mice.

Tebuconazole caused at high dose levels an increased incidence of tumours in mice in the following organ(s): liver. The mechanism of tumour formation is not considered to be relevant to man.

N,N-Dimethyldecanamide is not considered carcinogenic.

Based on a similar formulation.

Assessment toxicity to reproduction

Prothioconazole caused reproduction toxicity in a two-generation study in rats only at dose levels also toxic to the parent animals. The reproduction toxicity seen with Prothioconazole is related to parental toxicity.

Tebuconazole caused reproduction toxicity in a two-generation study in rats only at dose levels also toxic to the parent animals. The reproduction toxicity seen with Tebuconazole is related to parental toxicity.

N,N-Dimethyldecanamide is not considered a reproductive toxicant at non-maternally toxic dose levels.

Based on a similar formulation.

Assessment developmental toxicity

Prothioconazole caused developmental toxicity only at dose levels toxic to the dams. The developmental effects seen with Prothioconazole are related to maternal toxicity.

Tebuconazole caused developmental toxicity only at dose levels toxic to the dams. Tebuconazole caused an increased incidence of post implantation losses, an increased incidence of non-specific malformations.

N,N-Dimethyldecanamide did not cause developmental toxicity in rats and rabbits.
Based on a similar formulation.

Aspiration hazard

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

Further information

No further toxicological information is available

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment: The mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Section 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish:	LC50 (Oncorhynchus mykiss (rainbow trout)) 3.94 mg/l Exposure time: 96 h
Toxicity to aquatic Invertebrates:	EC50 (Daphnia magna (Water flea)) 8.8 mg/l Exposure time: 48 h
Chronic toxicity to aquatic invertebrates:	NOEC (Daphnia (water flea)): 0.010 mg/l Exposure time: 21 d The value mentioned relates to the active ingredient tebuconazole.
Toxicity to aquatic plants:	IC50 (Raphidocelis subcapitata (freshwater green alga)) 9.5 mg/l Growth rate; Exposure time: 72 h ErC50 (Skeletonema costatum) 0.03278 mg/l Exposure time: 72 h The value mentioned relates to the active ingredient prothioconazole. EC10 (Skeletonema costatum) 0.01427 mg/l Growth rate; Exposure time: 72 h The value mentioned relates to the active ingredient prothioconazole.

12.2 Persistence and degradability

Biodegradability: Prothioconazole is not readily biodegradable.
Tebuconazole is not readily biodegradable.
N,N-Dimethyldecanamide rapidly biodegradable.

Koc: Prothioconazole: Koc: 1765
Tebuconazole: Koc: 769

12.3 Bioaccumulative potential

Prothioconazole:	Bioconcentration factor (BCF) 19, Does not bioaccumulate.
Tebuconazole	Bioconcentration factor (BCF) 35 - 59 Does not bioaccumulate.
N,N-Dimethyldecanamide:	Does not bioaccumulate.

12.4 Mobility in soil

Mobility: Prothioconazole: Slight mobile in soils.
Tebuconazole: Slightly mobile in soils.

N,N-Dimethyldecanamide: Slightly mobile in soils.

12.5 Results of PBT and vPvB assessment

Prothioconazole: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).

N,N-Dimethyldecanamide: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).

Tebuconazole: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).

12.6 Endocrine disrupting properties

Product:

Assessment: The mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

Section 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: It is best to use all of the product in accordance with label directions. If it is necessary to dispose of unused product, please follow container label instructions and applicable local guidelines.

Contaminated packaging: Small containers (< 10 l or < 10 kg) should be rinsed thoroughly using an integrated pressure rinsing device, or, by manually rinsing three times. Add washings to sprayer at time of filling. Dispose of empty and cleaned packaging safely. Follow advice on product label and/or leaflet. Not completely emptied packagings should be disposed of as hazardous waste.

Section 14. TRANSPORT INFORMATION

Transport the product in accordance with the provisions of ADR for road, RID for rail, IMDG for the sea, and ICAO / IATA for air transport

14.1 UN Number

3082.

14.2 UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TEBUCONAZOLE, PROTHIOCONAZOLE SOLUTION)

14.3 Transport hazard class(es)

9

14.4 Packing group

III

14.5 Environmental hazards

Dangerous for the environment, Marine Pollutant.

14.6 Special precautions for user

See sections 6 to 8 of this Safety Data Sheet.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

Section 15. REGULATORY INFORMATION

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

This material may be subject to some or all of the following regulations (and any subsequent amendments). Users must ensure that any uses and restrictions as indicated on the label and/or leaflet are followed.

15.2 Chemical safety assessment

A chemical safety assessment is not required.

Section 16. OTHER INFORMATION

Full list of relevant hazard and precautionary statements that were not given in full in sections 2 and 3.

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes severe eye irritation.
H335	May cause respiratory irritation.
H361d	Suspected of damaging the unborn child
H400	Very toxic to aquatic organisms.
H410	Very toxic to aquatic organisms with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

The information presented in this document is accurate to the best of our knowledge at the date of its publication. However, the information given is designed only as a guide for the methods of handling, storage, use, transportation and disposal of the product and is not considered a warranty or quality specification. Life Scientific Limited cannot be held responsible for any loss or damage resulting from the handling, storage, use or disposal of the product. The information contained in this document relates only to this specific product.

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