

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

1.1 Product Identifier

Product Name: ORASO
Product Code: 073-01

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

Product Use: Agriculture – Fungicide

1.3 Details of the supplier of the safety data sheet

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

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 (EC) 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



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

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.

Precautionary statement:

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.

SP1 Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

2.3 Other Hazards

Special labelling of certain mixtures: To avoid risks to human health and environment comply with the instructions for use

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

For small fires:	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
For large fires:	Use alcohol-resistant foam or water spray.

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

Wear self-contained breathing apparatus. Fight fire from a safe distance and a protected location.

Section 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Do not breathe vapour/spray. Use personal protective clothing. Avoid contact with the skin, eyes and clothing.

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 exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

Section 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

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

Segregate from foods and animal feeds. Keep away from heat. Protect from direct sunlight. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of reach of children.

7.3 Specific end use(s)

For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

Section 8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 Control parameters

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

8.2 Exposure controls

When using this product refer to the label for details. In all other cases, use the following Personal Protective Equipment:

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.
Hand protection:	Wear suitable protective gloves (complying with EN 374). 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.
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

Appearance

Physical properties

Form:	Liquid
Colour:	Tan
Odour:	Aromatic

Chemical properties

pH:	5 - 7 at (1%) (20°C)
Melting point:	140.3 °C Prothioconazole 105 °C Tebuconazole
Boiling point/boiling range:	No data available
Flash point:	> 148 °C
Evaporation rate:	No data available
Flammability (solid, gas):	Non-flammable
Upper/lower flammability or explosive limits:	Not applicable
Vapour pressure:	No data available
Vapour density (air):	Not applicable
Density:	0.8 – 1.2 g/cm³ at 20 °C
Solubility(ies): Water	emulsifiable
Partition coefficient: n-octanol/water	Prothioconazole: log Pow: 3.82 at 20 °C at pH 7 Tebuconazole: log Pow: 3.7 N,N-Dimethyldecanamide: log Pow: 2.46
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	49.9 mPa.s at 20 °C
Explosive properties:	Non-explosive
Oxidising properties:	Non-oxidising

9.2 Other Information

None.

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 toxicological effects

Acute Oral Toxicity LD50 Rat:	> 2500 mg/kg
Acute Inhalation Toxicity LC50 Rat:	> 5.153 mg/l, 4 h. Based on test results obtained with similar product.
Acute Dermal Toxicity LD50 Rat:	> 4000 mg/kg
Acute Eye Irritation, Rabbit:	Irritating to eyes
Acute Skin Irritation, Rabbit:	Irritating to skin
Sensitisation, Guinea pig:	Not sensitising

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.

Section 12. ECOLOGICAL INFORMATION

12.1 Toxicity

LC ₅₀ Rainbow trout (96 h):	3.94 mg/L
EC ₅₀ Daphnia magna (48 h):	8.8 mg/L
IC ₅₀ Green algae (72 h):	9.5 mg/L
EC ₅₀ <i>Skeletonema costatum</i> (72h):	0.03278 mg/l

12.2 Persistence and degradability

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

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

12.3 Bioaccumulative potential

Prothioconazole, does not bioaccumulate.
N,N-Dimethyldecanamide does not bioaccumulate.
Tebuconazole does not bioaccumulate.

12.4 Mobility in soil

Mobility: Prothioconazole has slight mobility in soils.
N,N-Dimethyldecanamide has slight mobility in soils.
Tebuconazole: 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 Other adverse effects

No data available

Section 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Do not discharge into drains or rivers. Waste management is performed without endangering human health and without harming the environment, and in particular without risk to water, air, soil, fauna and flora.
Recycle or dispose of in accordance 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.
Contaminated packaging: Empty container completely, rinse three times. Keep the label on the recipient.

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

14.6 Special precautions for user

See sections 6-8 of this Safety Data Sheet

14.7 Transport in bulk according to Annex II of Marpol 73/78 and the IBC code

No data available

Section 15. REGULATORY INFORMATION

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

To avoid risks to human health and the environment, comply with the instructions for use.

15.2 Chemical safety assessment

None

Section 16. OTHER INFORMATION

Full text hazard statements mentioned in section 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 life.
H410 Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

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