amended



 PROLINE

 Version 12 / IRL
 Revision Date: 11.12.2024

 102000008022
 Print Date: 16.01.2025

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

1.1 Product identifier

Trade name PROLINE

**UFI** NR70-Q0VS-600J-CMH6 **Product code (UVP)** 05863929, 86252961

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

**Use** Fungicide

1.3 Details of the supplier of the safety data sheet

**Supplier** Bayer CropScience Ltd

Bayer Ltd

1st Floor, The Grange Offices The Grange, Brewery Road

Stillorgan

A94 H2K7 Co. Dublin

Ireland

**Telephone** +353 1 216 3300

Responsible Department Email: gb-bcs-crop-regulatory-affairs@bayer.com

1.4 Emergency telephone no.

Emergency telephone no. +44 330 678 3382 (24 hr) (charged as a standard international call to

the UK)

For Medical Professionals and Members of the Public:

You can also contact the relevant NPIS.

National Poisons Information Centre Dublin: 01 809 2166

#### **SECTION 2: HAZARDS IDENTIFICATION**

#### 2.1 Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended.

Eye irritation: Category 2

H319 Causes serious eye irritation.

Specific target organ toxicity - single exposure: Category 3

H335 May cause respiratory irritation. Short-term (acute) aquatic hazard: Category 1

amended



 PROLINE

 Version 12 / IRL
 Revision Date: 11.12.2024

 102000008022
 Print Date: 16.01.2025

H400 Very toxic to aquatic life.

Long-term (chronic) aquatic hazard: Category 1

H410 Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

Labelling in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended.

Hazard label for supply/use required.

#### Hazardous components which must be listed on the label:

Prothioconazole

N,N-Dimethyl decanamide





Signal word: Warning Hazard statements

H319 Causes serious eye irritation. H335 May cause respiratory irritation.

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 statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor/ physician.

P410 Protect from sunlight.

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.

#### 2.3 Other hazards

No additional hazards known beside those mentioned.

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).

Ecological information: The substance/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.

Toxicological information: The substance/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.

amended



PROLINE
Version 12 / IRL
Revision Date: 11.12.2024

102000008022 Print Date: 16.01.2025

#### **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

#### 3.2 Mixtures

#### **Chemical nature**

Emulsifiable concentrate (EC) Prothioconazole 250 g/l

#### **Hazardous components**

Hazard statements according to Regulation (EC) No. 1272/2008

Name	CAS-No. /	Classification	Conc. [%]
	EC-No. / REACH Reg. No.	REGULATION (EC) No 1272/2008	
Prothioconazole	178928-70-6	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	25.00
N,N-Dimethyl decanamide	14433-76-2 238-405-1 01-2119485027-36-XXXX	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Chronic 3, H412	> 20.00

#### **Further information**

Prothioconazole	178928-70-6	M-Factor: 10 (acute), 1 (chronic)

For the full text of the H-Statements mentioned in this Section, see Section 16.

#### **Particle characteristics**

This substance/ mixture does not contain nanoforms

#### **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. Get medical

attention if irritation develops and persists.

**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** Do NOT induce vomiting. Call a physician or poison control center

immediately. Rinse mouth.

amended



**PROLINE** 4/13 Version 12 / IRL Revision Date: 11.12.2024 102000008022 Print Date: 16.01.2025

4.2 Most important symptoms and effects, both acute and delayed

**Symptoms** No symptoms known or expected.

4.3 Indication of any immediate medical attention and special treatment needed

**Treatment** 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 (HCI), Hydrogen cyanide (hydrocyanic acid), Carbon monoxide (CO),

Sulphur oxides, Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective

equipment 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

fire fighting to enter drains or water courses.

**SECTION 6: ACCIDENTAL RELEASE MEASURES** 

6.1 Personal precautions, protective equipment and emergency procedures

**Precautions** 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

Methods for 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. Keep in

suitable, closed containers for disposal.

Additional advice Check also for any local site procedures.

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.

amended



PROLINE
Version 12 / IRL
Revision Date: 11.12.2024

102000008022 Revision Date: 11.12.2024 Print Date: 16.01.2025

#### **SECTION 7: HANDLING AND STORAGE**

#### 7.1 Precautions for safe handling

Advice on safe handling No specific precautions required when handling unopened

packs/containers; follow relevant manual handling advice. Ensure

adequate ventilation.

Advice on protection against fire and explosion

No special precautions required.

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 frost. Keep away from direct sunlight.

Advice on common storage

Keep away from food, drink and animal feedingstuffs.

Suitable materials

HDPE - steel case

HDPE (high density polyethylene)

Coex HDPE/EVOH Coex HDPE/PA

7.3 Specific end use(s)

Refer to the label and/or leaflet.

#### **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### 8.1 Control parameters

Components	CAS-No.	Control parameters	Update	Basis
Prothioconazole	178928-70-6	1.4 mg/m3 (SK-ABS)		OES BCS*

\*OES BCS: Internal Bayer AG, Crop Science Division "Occupational Exposure Standard"

#### 8.2 Exposure controls

#### Personal protective equipment

Formulated product

**Respiratory protection** Wear respirator with an organic vapours and gas filter mask

(protection factor 10) conforming to EN140 type A 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.

Hand protection Please observe the instructions regarding permeability and

amended



 PROLINE

 Version 12 / IRL
 Revision Date: 11.12.2024

 102000008022
 Print Date: 16.01.2025

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.

Material Nitrile rubber
Rate of permeability > 480 min
Glove thickness > 0.4 mm
Protective index Class 6

Directive Protective gloves complying with EN

374.

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

**Skin and body 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.

#### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

#### 9.1 Information on basic physical and chemical properties

Form Liquid, clear to slightly turbid

**Colour** tan

**Odour** aromatic

Odour Threshold

Melting point/ range

Boiling Point

No data available

No data available

No data available

No data available

Upper explosion limit

No data available

No data available

Flash point 152 °C Auto-ignition temperature 340 °C

Self-accelarating decomposition temperature (SADT)

No data available

amended



 PROLINE

 Version 12 / IRL
 Revision Date: 11.12.2024

 102000008022
 Print Date: 16.01.2025

**pH** 5.0 - 6.0 (1 %) (23 °C) (deionized water)

Viscosity, dynamic No data available

Viscosity, kinematic 35.1 mm²/s (40 °C) Water solubility No data available

Partition coefficient: n-

octanol/water

Prothioconazole: log Pow: 3.82 (20 °C) (pH 7)

N,N-Dimethyldecanamide: log Pow: 2.46

Surface tension 29.9 mN/m (20 °C)

Vapour pressure No data available

**Density** ca. 1.00 g/cm³ (20 °C)

Relative density

No data available

Relative vapour density

No data available

Assessment nano particles This substance/ mixture does not contain nanoforms

Particle size No data available

9.2 Other information

ExplosivityNot explosiveOxidizing propertiesNo data availableEvaporation rateNo data available

Other physico-chemical

properties

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 materials** Store only in the original container.

10.6 Hazardous decomposition products

No decomposition products expected under normal conditions of use.

amended



PROLINE
Version 12 / IRL
Revision Date: 11.12.2024

102000008022 Print Date: 16.01.2025

#### **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

Acute inhalation toxicity LC50 (Rat) > 5 mg/l

Exposure time: 4 h

Highest attainable concentration.

Determined in the form of a respirable aerosol.

Irritating to respiratory system.

The value mentioned relates to N,N-dimethylacetamide.

Acute dermal toxicity LD50 (Rat) > 4,000 mg/kg Skin corrosion/irritation No skin irritation (Rabbit)

Test conducted with a similar formulation.

Serious eye damage/eye

irritation

Irritating to eyes. (Rabbit)

Test conducted with a similar formulation.

Respiratory or skin sensitisation

Skin: Non-sensitizing. (Guinea pig)
OECD Test Guideline 406, Buehler test
Test conducted with a similar formulation.

#### Assessment STOT Specific target organ toxicity - single exposure

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

N,N-Dimethyldecan-1-amide: May cause respiratory irritation.

#### Assessment STOT Specific target organ toxicity - repeated exposure

Prothioconazole 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.

#### 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.

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

#### **Assessment carcinogenicity**

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

N,N-Dimethyldecanamide is not considered carcinogenic.

#### 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.

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

#### 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.

N,N-Dimethyldecanamide did not cause developmental toxicity in rats and rabbits.

#### **Aspiration hazard**

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

amended



 PROLINE

 Version 12 / IRL
 Revision Date: 11.12.2024

 102000008022
 Print Date: 16.01.2025

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

Assessment The substance/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)) 4.02 mg/l

Exposure time: 96 h

**Toxicity to aquatic** 

**invertebrates** Exposure time: 48 h

Toxicity to aquatic plants EC50 (Raphidocelis subcapitata (freshwater green alga)) 12.7 mg/l

Growth rate; Exposure time: 72 h

ErC50 (Skeletonema costatum) 0.03278 mg/l

EC50 (Daphnia magna (Water flea)) 2.9 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:

Not rapidly biodegradable N,N-Dimethyldecanamide: rapidly biodegradable

**Koc** Prothioconazole: Koc: 1765

12.3 Bioaccumulative potential

**Bioaccumulation** Prothioconazole: Bioconcentration factor (BCF) 19

Does not bioaccumulate. N,N-Dimethyldecanamide: Does not bioaccumulate.

12.4 Mobility in soil

Mobility in soil Prothioconazole: Slightly mobile in soils

N,N-Dimethyldecanamide: Slightly mobile in soils

12.5 Results of PBT and vPvB assessment

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

amended



 PROLINE

 Version 12 / IRL
 Revision Date: 11.12.2024

 102000008022
 Print Date: 16.01.2025

considered to be very persistent and very bioaccumulative (vPvB).

12.6 Endocrine disrupting properties

Assessment The substance/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

Additional ecological

information

No other effects to be mentioned.

#### **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.

Waste key for the unused 02 01 08

product

02 01 08\* agrochemical waste containing hazardous substances

#### **SECTION 14: TRANSPORT INFORMATION**

#### ADR/RID/ADN

**Tunnel Code** 

14.1 UN number **3082** 

14.2 Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(PROTHIOCONAZOLE SOLUTION)

14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environm. Hazardous Mark
Hazard no.
90

This classification is in principle not valid for carriage by tank vessel on inland waterways. Please refer to the manufacturer for further information.

**IMDG** 

14.1 UN number 3082

14.2 Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(PROTHIOCONAZOLE SOLUTION)

14.3 Transport hazard class(es)

amended



 PROLINE

 Version 12 / IRL
 Revision Date: 11.12.2024

 102000008022
 Print Date: 16.01.2025

14.4 Packing group III
14.5 Marine pollutant YES

IATA

14.1 UN number **3082** 

14.2 Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(PROTHIOCONAZOLE SOLUTION)

14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environm. Hazardous Mark
YES

#### 14.6 Special precautions for user

See sections 6 to 8 of this Safety Data Sheet.

#### 14.7 Transport in bulk according to IMO instruments

No transport in bulk according to the IBC Code.

#### **SECTION 15: REGULATORY INFORMATION**

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

#### **Republic of Ireland Regulations**

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

#### Supply and Use

European Communities (Prohibition of Certain Active Substances in Plant Protection Products) Regulations 1981 (SI No 320/1981)

European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations 2003 (SI No 83/2003)

European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations 2001 (SI No 624/2001

2010 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001 (SI No 619/2001)

#### **Waste Treatment**

**Landfill Directive** 

Regulation on Substances That Deplete the Ozone Layer 1994 (EEC/3093/94)

#### **Further information**

WHO-classification: III (Slightly hazardous)

#### 15.2 Chemical safety assessment

A chemical safety assessment is not required.

amended



 PROLINE

 Version 12 / IRL
 Revision Date: 11.12.2024

 102000008022
 Print Date: 16.01.2025

#### **SECTION 16: OTHER INFORMATION**

#### Text of the hazard statements mentioned in Section 3

H315 Causes skin irritation.

H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

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.

#### Abbreviations and acronyms

ADN European Agreement concerning the International Carriage of Dangerous Goods by

**Inland Waterways** 

ADR European Agreement concerning the International Carriage of Dangerous Goods by

Road

ATE Acute toxicity estimate

CAS-Nr. Chemical Abstracts Service number

Conc. Concentration

EC-No. European community number ECx Effective concentration to x %

EINECS European inventory of existing commercial substances

ELINCS European list of notified chemical substances

ELV Exposure Limit Value
EN European Standard
EU European Union

IATA International Air Transport Association

IBC International Code for the Construction and Equipment of Ships Carrying Dangerous

Chemicals in Bulk (IBC Code) Inhibition concentration to x %

IMDG International Maritime Dangerous Goods

LCx Lethal concentration to x %

LDx Lethal dose to x %

**IC**x

LOEC/LOEL Lowest observed effect concentration/level

MARPOL: International Convention for the prevention of marine pollution from ships

N.O.S. Not otherwise specified

NOEC/NOEL No observed effect concentration/level

OECD Organization for Economic Co-operation and Development

RID Regulations concerning the International Carriage of Dangerous Goods by Rail

SI Statutory Instrument
TWA Time weighted average

UN United Nations

WHO World health organisation

The information contained within this Safety Data Sheet is in accordance with the guidelines established by Regulation (EU) 1907/2006 and Regulation (EU) 2020/878 amending Regulation (EU) No 1907/2006 and any subsequent amendments. This data sheet complements the user's instructions, but does not replace them. The information it contains is based on the knowledge available about the product concerned at the time it was compiled. Users are further reminded of the possible risks of using a product for purposes other than those for which it was intended. The required information complies with current EEC legislation. Addressees are requested to observe any additional national requirements.



 PROLINE

 Version 12 / IRL
 Revision Date: 11.12.2024

 102000008022
 Print Date: 16.01.2025

**Reason for Revision:** Safety Data Sheet according to Regulation (EU) No. 2020/878.

Checked and revised for editorial purposes due to adjustments according to the current Annex II of the REACH regulation.

The following sections have been revised: Section 13. Disposal

considerations.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.