



PROSARO

Version 9 / GB
102000007908

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Revision Date: 21.03.2023
Print Date: 21.03.2023

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

1.1 Product identifier

Trade name PROSARO
Product code (UVP) 05676428, 81782423
UFI VN70-706C-W002-Q8X4 (for Northern Ireland only) (voluntary notification)

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

Use Fungicide
Restrictions on use See product label for restrictions.

1.3 Details of the supplier of the safety data sheet

Supplier Bayer CropScience Limited
230 Cambridge Science Park
Milton Road
Cambridge
Cambridgeshire CB4 0WB
United Kingdom
Telephone +44(0)1223 226500
Telefax +44(0)1223 426240
Responsible Department Email: gb-bcs-crop-regulatory-affairs@bayer.com
FOR IRELAND & NORTHERN IRELAND: Bayer CropScience Ltd
Bayer Ltd
1st Floor, The Grange Offices
The Grange, Brewery Road
Stillorgan
Co. Dublin
A94 H2K7
Ireland
Telephone +353 1 216 3300

1.4 Emergency telephone no.

Emergency telephone no. 00800 1020 3333 (24 hr) (not available on non-contract mobile phones)

For Medical Professionals: You can also contact the relevant NPIS.
For Members of the Public: You can also contact NHS111 (for GB) or your local GP (for Northern Ireland).

National Poisons Information Centre Dublin +353-1-809 2166 (available from 8 am to 10 pm every day)



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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.

Skin irritation: Category 2

H315 Causes skin irritation.

Eye irritation: Category 2

H319 Causes serious eye irritation.

Specific target organ toxicity - single exposure: Category 3

H335 May cause respiratory irritation.

Reproductive toxicity: Category 2

H361d Suspected of damaging the unborn child.

Acute aquatic toxicity: Category 1

H400 Very toxic to aquatic life.

Chronic aquatic toxicity: 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:

- Tebuconazole
- Prothioconazole
- N,N-Dimethyl decanamide



Signal word: Warning

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H410 Very toxic to aquatic life with long lasting effects.

H361d Suspected of damaging the unborn child.

EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary statements

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

P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor/ physician.

P391 Collect spillage.

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P410 Protect from sunlight.
P501 Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean 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).
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).
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.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**3.2 Mixtures****Chemical nature**

Emulsifiable concentrate (EC)
Prothioconazole/Tebuconazole 125:125 /g/l

Hazardous components

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

Name	CAS-No. / EC-No. / REACH Reg. No.	Classification	Conc. [%]
		REGULATION (EC) No 1272/2008	
Prothioconazole	178928-70-6	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	12.76
Tebuconazole	107534-96-3	Acute Tox. 4, H302 Repr. 2, H361d Aquatic Acute 1, H400 Aquatic Chronic 1, H410	12.76
N,N-Dimethyl decanamide	14433-76-2 01-2119485027-36-XXXX	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Chronic 3, H412	> 20

Further information

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



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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. 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

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 (HCl), 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.

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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/m ³ (SK-ABS)		OES BCS*
Tebuconazole	107534-96-3	0.2 mg/m ³ (SK-ABS)		OES BCS*

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

8.2 Exposure controls

Refer to COSHH assessment (Control of Substances Hazardous to Health (Amendment) Regulations 2004). Engineering controls should be used in preference to personal protective equipment wherever practicable. Refer also to COSHH Essentials.

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.

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.

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.

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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	No data available
Melting point/range	No data available
Boiling Point	No data available
Flammability	No data available
Upper explosion limit	No data available
Lower explosion limit	No data available
Flash point	> 148 °C
Auto-ignition temperature	No data available
Self-accelarating decomposition temperature (SADT)	No data available
pH	5.0 - 7.0 (1 %) (23 °C) (deionized water)
Viscosity, dynamic	49.9 mPa.s (20 °C)
Viscosity, kinematic	No data available
Water solubility	emulsifiable
Partition coefficient: n-octanol/water	Prothioconazole: log Pow: 3.82 (20 °C) (pH 7) Tebuconazole: log Pow: 3.7 N,N-Dimethyldecanamide: log Pow: 2.46
Surface tension	ca. 29.1 mN/m (20 °C)
Vapour pressure	No data available
Density	ca. 0.98 g/cm ³ (20 °C)
Relative density	No data available
Relative vapour density	No data available
Assessment nano particles	This substance/ mixture does not contain nanoforms

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Particle size	No data available
9.2 Other information	
Explosivity	Not explosive
Oxidizing properties	No oxidizing properties
Evaporation rate	No 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.

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) > 5.153 mg/l Exposure time: 4 h
Acute dermal toxicity	LD50 (Rat) > 4,000 mg/kg
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 STOT Specific target organ toxicity – single exposure

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



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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.
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.

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.

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.

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.

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.

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

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.

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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: Not rapidly biodegradable Tebuconazole: Not rapidly biodegradable N,N-Dimethyldecanamide: rapidly biodegradable
Koc	Prothioconazole: Koc: 1765 Tebuconazole: Koc: 769

12.3 Bioaccumulative potential

Bioaccumulation	Prothioconazole: Bioconcentration factor (BCF) 19 Does not bioaccumulate. Tebuconazole: Bioconcentration factor (BCF) 35 - 59 Does not bioaccumulate. N,N-Dimethyldecanamide: Does not bioaccumulate.
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12.4 Mobility in soil

Mobility in soil	Prothioconazole: Slightly mobile in soils Tebuconazole: Slightly mobile in soils N,N-Dimethyldecanamide: Slightly mobile in soils
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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). 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).
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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).

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**

In accordance with current regulations and, if necessary, after consultation with the site operator and/or with the responsible authority, the product may be taken to a waste disposal site or incineration plant. Advice may be obtained from the local waste regulation authority (part of the Environment Agency in the UK).

SECTION 14: TRANSPORT INFORMATION**ADR/RID/ADN**

14.1 UN number	3082
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TEBUCONAZOLE, PROTHIOCONAZOLE SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Environm. Hazardous Mark	YES
Hazard no.	90
Tunnel Code	-

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. (TEBUCONAZOLE, PROTHIOCONAZOLE SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Marine pollutant	YES

IATA

14.1 UN number	3082
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14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TEBUCONAZOLE, PROTHIOCONAZOLE SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Environm. Hazardous Mark	YES

UK 'Carriage' Regulations

14.1 UN number	3082
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TEBUCONAZOLE, PROTHIOCONAZOLE SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Environm. Hazardous Mark	YES
Emergency action code	3Z

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****UK and Northern Ireland Regulatory References**

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.

Transport

Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009 No 1348)

Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 (SI 1997 No 2367)

Air Navigation Dangerous Goods Regulations 2002 (SI 2002 No 2786)

Supply and Use

Chemical (Hazard Information and Packaging for Supply) Regulations 2009 (SI 2009 No 716)

Chemical (Hazard Information and Packaging for Supply) (Northern Ireland) Regulations 2009

Control of Substances Hazardous to Health Regulations 2002 (SI 2002 No 2677)

EH40 Occupational Exposure Limits - Table 1 List of approved workplace exposure limits

Control of Pesticide Regulations 1986

Dangerous Substances and Explosive Atmospheres Regulations 2002

Waste Treatment

Environmental Protection Act 1990, Part II

Environmental Protection (Duty of Care) Regulations 1991

The Waste Management Licensing Regulations 1994 (as amended)

Hazardous Waste Regulations 2005 (Replacing Special Waste Regulations 1996 as amended)

Landfill Directive

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Regulation on Substances That Deplete the Ozone Layer 1994 (EEC/3093/94)
Water Resources Act 1991
Anti-Pollution Works Regulations 1999

Further information

WHO-classification: III (Slightly hazardous)

SECTION 16: OTHER INFORMATION**Text of the hazard statements mentioned in Section 3**

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious 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.

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 %
EH40 WEL	Worker Exposure Limit
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
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)
ICx	Inhibition concentration to x %
IMDG	International Maritime Dangerous Goods
LCx	Lethal concentration to x %
LDx	Lethal dose to x %
LOEC/LOEL	Lowest observed effect concentration/level
MARPOL	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



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The above information is intended to give general health and safety guidance on the storage and transport of the product.

It is not intended to apply to the use of the product for which purposes the product label and any appropriate technical usage literature available should be consulted and any relevant licenses, consents or approvals complied with.

The requirements or recommendations of any relevant site or working procedure, system or policy in force or arising from any risk assessment involving the substance or product should take precedence over any of the guidance contained in this safety data sheet where there is a difference in the information given.

The information provided in this safety data sheet is accurate at the date of publication and will be updated as and when appropriate.

No liability will be accepted for any injury, loss or damage resulting from any failure to take account of information or advice contained in this safety data sheet.

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