



PROSARO

Version 9 / IRL
102000007908

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Revision Date: 21.03.2023
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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name PROSARO
UFI VN70-706C-W002-Q8X4
Product code (UVP) 05676428, 81782423

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 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. 00800 1020 3333 (24 hr) (not available on non-contract mobile phones)

For Medical Professionals: You can also contact Dublin NPIS.
For Members of the Public: You can also contact 01 809 2166 (for Republic of Ireland).

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.



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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.
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).
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)

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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	107534-96-3 403-640-2	Acute Tox. 4, H302 Repr. 2, H361d Aquatic Acute 1, H400 Aquatic Chronic 1, H410	12.76
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

Further information

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



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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.

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.

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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. 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 feedingstuffs.

Suitable materials HDPE (high density polyethylene)

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**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

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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.

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

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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
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.

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- 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.
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

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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.

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:

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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.

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

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).

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**

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.

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Dispose of empty and cleaned packaging safely.
Follow advice on product label and/or leaflet.
Triple rinse containers.
Do not re-use empty containers.
Not completely emptied packagings should be disposed of as hazardous waste.

Waste key for the unused product**02 01 08*** agrochemical waste containing hazardous substances**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
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

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.



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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 amendments). 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.

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

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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)
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

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.

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.

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