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RUDISVersion 4 / IRL
102000007878

Revision Date: 11.12.2024
Print Date: 16.01.2025

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

1.1 Product identifier

Trade name RUDIS

UFI U252-F0U2-U00H-FH5S (voluntary notification)

Product code (UVP) 05664330

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.

Short-term (acute) aquatic hazard: Category 1 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

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RUDISVersion 4 / IRL
102000007878

Revision Date: 11.12.2024
Print Date: 16.01.2025

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



Signal word: Warning

Hazard statements

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, 1,2-benzisothiazolin-3-one, reaction mass of 5-chloro-2- methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1). May produce an allergic

reaction.

Precautionary statements

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).

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

Suspension concentrate (=flowable concentrate)(SC) Prothioconazole 480 g/l



 RUDIS

 Version 4 / IRL
 Revision Date: 11.12.2024

 102000007878
 Print Date: 16.01.2025

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	40.3
1,2-Benzisothiazol-3(2H)- one	2634-33-5 220-120-9 01-2120761540-60-xxxx	Acute Tox. 4, H302 Acute Tox. 2, H330 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 2, H411	>= 0.005 - < 0.05
reaction mass of 5-chloro- 2- methyl-2H-isothiazol-3- one and 2-methyl-2H- isothiazol-3- one (3:1)	55965-84-9	Acute Tox. 3, H301 Acute Tox. 2, H310 Acute Tox. 2, H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	>= 0.00015 - < 0.0015
Urea	57-13-6 200-315-5 01-2119463277-33-xxxx	Not classified	>= 1

Further information

Prothioconazole	178928-70-6	M-Factor: 10 (acute), 1 (chronic)
1,2-Benzisothiazol- 3(2H)-one1,2- Benzisothiazol-3(2H)- one	2634-33-5	M-Factor: 1 (acute), 1 (chronic)
1,2-Benzisothiazol- 3(2H)-one	2634-33-5	SCL: Skin Sens. 1; H317: SCL >= 0.05 %
1,2-Benzisothiazol- 3(2H)-one	2634-33-5	Inhalation: ATE = 0.21 mg/l (dust/mist)
1,2-Benzisothiazol- 3(2H)-one	2634-33-5	Oral: ATE = 450 mg/kg
reaction mass of 5- chloro-2- methyl-2H- isothiazol-3-one and 2- methyl-2H-isothiazol-3- one (3:1)	55965-84-9	M-Factor: 100 (acute), 100 (chronic)
reaction mass of 5- chloro-2- methyl-2H- isothiazol-3-one and 2- methyl-2H-isothiazol-3- one (3:1)	55965-84-9	SCL: Skin Corr. 1C; H314: SCL >= 0.6 %
reaction mass of 5- chloro-2- methyl-2H- isothiazol-3-one and 2- methyl-2H-isothiazol-3-	55965-84-9	SCL: Skin Irrit. 2; H315: SCL 0.06 - < 0.6 %

amended



RUDISVersion 4 / IRL
102000007878

Revision Date: 11.12.2024
Print Date: 16.01.2025

one (3:1)		
reaction mass of 5- chloro-2- methyl-2H- isothiazol-3-one and 2- methyl-2H-isothiazol-3- one (3:1)	55965-84-9	SCL: Eye Irrit. 2; H319: SCL 0.06 - < 0.6 %
reaction mass of 5- chloro-2- methyl-2H- isothiazol-3-one and 2- methyl-2H-isothiazol-3- one (3:1)	55965-84-9	SCL: Skin Sens. 1A; H317: SCL >= 0.0015 %
reaction mass of 5- chloro-2- methyl-2H- isothiazol-3-one and 2- methyl-2H-isothiazol-3- one (3:1)	55965-84-9	SCL: Eye Dam. 1; H318: SCL >= 0.6 %

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.

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.

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. Gastric lavage is not normally required.

However, if a significant amount (more than a mouthful) has been ingested, administer activated charcoal and sodium sulphate.

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RUDISVersion 4 / IRL
102000007878

Revision Date: 11.12.2024
Print Date: 16.01.2025

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Water spray, Carbon dioxide (CO2), Foam, Sand

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 cyanide (hydrocyanic acid), Carbon monoxide (CO), Carbon dioxide (CO2), Nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride (HCI)

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). Collect and transfer the product

into a properly labelled and tightly closed container. Clean

contaminated floors and objects thoroughly, observing environmental

regulations.

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

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

Keep away from heat and sources of ignition.

amended



RUDISVersion 4 / IRL
102000007878

Revision Date: 11.12.2024
Print Date: 16.01.2025

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 a place accessible by authorized persons only. Keep containers tightly closed in a dry, cool and well-ventilated place. Store in original

container. Keep away from direct sunlight.

Advice on common storage Keep away from food, drink and animal feedingstuffs.

Suitable materials HDPE (high density polyethylene)

HDPE - steel case

HDPE (high density polyethylene) -fluorinated

Coex HDPE/EVOH/HDPE

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*
Urea	57-13-6	10 mg/m3 (TWA)		OES BCS*

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

8.2 Exposure controls

Personal protective equipment

Formulated product

Respiratory protection Respiratory protection is not required under anticipated

circumstances of exposure.

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

amended



 RUDIS

 Version 4 / IRL
 Revision Date: 11.12.2024

 102000007878
 Print Date: 16.01.2025

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form suspension

Colour white to light beige Odour weak, characteristic **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 $> 96 \, ^{\circ}\text{C}$ Auto-ignition temperature $> 600 \, ^{\circ}\text{C}$

Self-accelarating decomposition temperature

No data available

(SADT)

pH 5.5 - 7.5 (100 %) (23 °C)

Viscosity, dynamic 250 - 500 mPa.s (20 °C)

Velocity gradient 20 /s 100 - 180 mPa.s (20 °C) Velocity gradient 100 /s

Viscosity, kinematic 332 mm²/s (20 °C) Shear rate of 20/sec

116 mm²/s (20 °C) Shear rate of 100/sec

272 mm²/s (40 °C) Shear rate of 20/sec 88 mm²/s (40 °C) Shear rate of 100/sec

amended



 RUDIS

 Version 4 / IRL
 Revision Date: 11.12.2024

 102000007878
 Print Date: 16.01.2025

Water solubility miscible

Partition coefficient: n-

octanol/water

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

Vapour pressure No data available

Density ca. 1.19 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

Explosivity Not explosive

92/69/EEC, A.14 / OECD 113

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 ofNo hazardous reactions when stored and handled according to

hazardous reactions 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 cut-off (Rat) 2,500 mg/kg

Acute inhalation toxicity LC50 (Rat) > 1.582 mg/l

Exposure time: 4 h

amended



RUDISVersion 4 / IRL
102000007878

Revision Date: 11.12.2024
Print Date: 16.01.2025

Highest attainable concentration.

Acute dermal toxicity LD50 (Rat) > 5,000 mg/kg
Skin corrosion/irritation Mild skin irritation. (Rabbit)
Serious eye damage/eye Mild eye irritation. (Rabbit)

irritation

Respiratory or skin Skin: Non-sensitizing. (Guinea pig)

sensitisation OECD Test Guideline 406, Magnusson & Kligman test

Assessment STOT Specific target organ toxicity - single exposure

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

Assessment STOT Specific target organ toxicity - repeated exposure

Prothioconazole 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.

Assessment carcinogenicity

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

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.

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.

Aspiration hazard

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

Further information

Information given is based on data obtained from similar substances.

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)) 4.54 mg/l

amended



RUDISVersion 4 / IRL
102000007878

Revision Date: 11.12.2024
Print Date: 16.01.2025

Exposure time: 96 h

Toxicity to aquatic invertebrates

EC50 (Daphnia magna (Water flea)) 1.62 mg/l

Exposure time: 48 h

Toxicity to aquatic plants EC50 (Raphidocelis subcapitata (freshwater green alga)) 2.16 mg/l

Growth rate; Exposure time: 72 h

EC50 (Lemna gibba (gibbous duckweed)) 3.16 mg/l

Exposure time: 168 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

Koc Prothioconazole: Koc: 1765

12.3 Bioaccumulative potential

Bioaccumulation Prothioconazole: Bioconcentration factor (BCF) 19

Does not bioaccumulate.

12.4 Mobility in soil

Mobility in soil Prothioconazole: 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).

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.

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RUDISVersion 4 / IRL
Revision Date: 11.12.2024
102000007878
Print Date: 16.01.2025

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

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.

(PROTHIOCONAZOLE SOLUTION)

14.3 Transport hazard class(es) 9
14.4 Packing 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.

(PROTHIOCONAZOLE SOLUTION)

14.3 Transport hazard class(es) 9
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.

amended



RUDISVersion 4 / IRL
102000007878

Revision Date: 11.12.2024
Print Date: 16.01.2025

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.

SECTION 16: OTHER INFORMATION

Text of the hazard statements mentioned in Section 3

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations and acronyms

ADN	European Agreement co	ncerning the International	Carriage of Dangerous	Goods by
ADIN	Lui opean Agreement co	nicerining the international	Carriage of Dangerous	Occus by

Inland Waterways

ADR European Agreement concerning the International Carriage of Dangerous Goods by

Road

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RUDISVersion 4 / IRL
102000007878

Revision Date: 11.12.2024
Print Date: 16.01.2025

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 %

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.

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.