According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : thermodent® neutralizer Unique Formula Identifier : ES50-3026-8000-5EVE

(UFI)

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

Use of the Sub- : Decalcification agent

stance/Mixture

Recommended restrictions

on use

Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Producer : Schülke & Mayr GmbH

Robert-Koch-Str. 2

22851 Norderstedt

Germany

Telephone: +49 (0)40/ 52100-0 Telefax: +49 (0)40/ 52100318

mail@schuelke.com www.schuelke.com

Supplier : Schülke & Mayr UK Ltd.

Cygnet House

1, Jenkin Road, Meadowhall

Sheffield S9 1AT United Kingdom

Telephone: +44 114 254 35 00 Telefax: +44 114 254 35 01 mail.uk@schulke.com

E-mail address of person

responsible for the SDS/Contact person

Application Specialists +49 (0)40/ 521 00 666 AD@schuelke.com

(Schülke & Mayr UK Ltd.: +44-1142543500)

1.4 Emergency telephone number

Emergency telephone num-

ber

Carechem 24 International:+44 1235 239670

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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019)

Corrosive to metals, Category 1 H290: May be corrosive to metals.

Eye irritation, Category 2 H319: Causes serious eye irritation.

Specific target organ toxicity - single exposure, Category 3, Respiratory system

H335: May cause respiratory irritation.

Specific target organ toxicity - single exposure, Category 3, Respiratory system

H335: May cause respiratory irritation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019)

Hazard pictograms



Signal word : Warning

Hazard statements : H290 May be corrosive to metals.

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

Precautionary statements : Prevention:

P261 Avoid breathing vapours.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/

attention.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Solution of the following substances with harmless additives.

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
1,2,3-Propanetricarboxylic acid, 2-	5949-29-1	Eye Irrit. 2; H319	>= 50 - < 70
hydroxy-, monohydrate	201-069-1	STOT SE 3; H335	
		(Respiratory sys-	
	01-2119457026-42-	tem)	
	XXXX	,	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Take off all contaminated clothing immediately.

If inhaled : If breathed in, move person into fresh air.

In case of skin contact : Wash with water and soap as a precaution.

If symptoms persist, call a physician.

In case of eye contact : In the case of contact with eyes, rinse immediately with plenty

of water and seek medical advice.

If eye irritation persists, consult a specialist.

If swallowed : Rinse mouth with water.

Give small amounts of water to drink. Consult a physician if necessary.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Treat symptomatically.

Risks : Causes serious eye irritation.

May cause respiratory irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : For specialist advice physicians should contact the Poisons

Information Service.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Dry powder

Foam

Water spray jet Carbon dioxide (CO2)

Unsuitable extinguishing

media

Do NOT use water jet.

5.2 Special hazards arising from the substance or mixture

ucts

Hazardous combustion prod- : No hazardous combustion products are known

No hazardous combustion products are known

5.3 Advice for firefighters

for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions Avoid subsoil penetration.

6.3 Methods and material for containment and cleaning up

Wipe up with absorbent material (e.g. cloth, fleece). Methods for cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel,

acid binder, universal binder, sawdust).

6.4 Reference to other sections

see Section 8 + 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling Never mix concentrates directly.

Advice on protection against :

fire and explosion

No special protective measures against fire required.

Hygiene measures Keep away from food and drink.

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7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Store at room temperature in the original container.

Further information on stor-

age conditions

Keep away from heat. Keep container tightly closed. Recom-

mended storage temperature: 5 - 25°C

Advice on common storage : No materials to be especially mentioned.

7.3 Specific end use(s)

Specific use(s) : none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
1,2,3-Propanetricarboxylic acid,	Fresh water	0.44 mg/l
2-hydroxy-, monohydrate		_
	Marine water	0.044 mg/l
	Fresh water sediment	7.52 mg/kg
	Marine sediment	0.752 mg/kg
	Soil	29.2 mg/kg

8.2 Exposure controls

Personal protective equipment

Eye/face protection : Safety glasses with side-shields conforming to EN166

Hand protection

Directive : The selected protective gloves have to satisfy the specifica-

tions of Regulation (EU) 2016/425 and the standard EN 374

derived from it.

Remarks : Splash protection: disposable nitrile rubber gloves e.g.

Dermatril (layer thickness: 0.11 mm) made by KCL or gloves from other manufacturers offering the same protection. Prolonged contact: Nitrile rubber gloves e.g. Camatril (>480 Min., layer thickness: 0,40 mm) or butyl rubber gloves e.g. Butoject (>480 Min., layer thickness: 0,70 mm) made by KCL or gloves from other manufacturers offering the same protec-

tion.

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : No personal respiratory protective equipment normally re-

quired.

Protective measures : Avoid contact with skin and eyes.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid

Colour : colourless

Odour : nearly odourless

Odour Threshold : not determined

pH : 2 (20 °C)

Concentration: 100 %

Melting point/freezing point : ca. 0 °C

Decomposition temperature Not applicable

Boiling point/boiling range : ca. 100 °C

Flash point : Not applicable

Evaporation rate : No data available

Upper explosion limit / Upper

flammability limit

Not applicable

Lower explosion limit / Lower

flammability limit

Not applicable

Vapour pressure : ca. 25 hPa (20 °C)

Relative vapour density : No data available

Density : ca. 1.17 g/cm3 (20 °C)

Solubility(ies)

Water solubility : completely soluble (20 °C)

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

Viscosity

Viscosity, dynamic : ca. 4 mPa*s

Method: ISO 3219

Explosive properties : No data available

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

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Flammability (liquids) : Does not sustain combustion.

Metal corrosion rate : > 6.25 mm/a

Corrosive to metals Aluminium and Mild steel

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

The product is chemically stable.

10.3 Possibility of hazardous reactions

Hazardous reactions : None reasonably foreseeable.

10.4 Conditions to avoid

Conditions to avoid : Protect from frost, heat and sunlight.

10.5 Incompatible materials

Materials to avoid : Metals

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Not classified based on available information.

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Acute toxicity (other routes of : LD50 intravenous (Rat): 725 mg/kg

administration)

Skin corrosion/irritation

Not classified based on available information.

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

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> Rabbit Species

Mild skin irritation Result

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

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Species Rabbit

OECD Test Guideline 405 Method

Result Eve irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Method **OECD Test Guideline 406**

Result Does not cause skin sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Test Type: Ames test Genotoxicity in vitro

Test system: Salmonella typhimurium

Concentration: 0 - 5 mg/ plate

Method: Mutagenicity (Salmonella typhimurium - reverse mu-

tation assay) Result: negative

Test Type: Micronucleus test Test system: Human lymphocytes

Method: Mutagenicity (in vitro mammalian cytogenetic test)

Result: positive

Genotoxicity in vivo Species: Rat

Application Route: Oral

Method: OECD Test Guideline 475

Result: negative

sessment

Germ cell mutagenicity- As- : In vitro tests did not show mutagenic effects

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Carcinogenicity

Not classified based on available information.

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Carcinogenicity - Assess- : Not classifiable as a human carcinogen.

ment

Reproductive toxicity

Not classified based on available information.

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Effects on foetal develop- : Species: Rat

ment Application Route: Oral

General Toxicity Maternal: NOAEL: 2,500 mg/kg body weight

Reproductive toxicity - As- : No toxicity to reproduction

sessment

STOT - single exposure

May cause respiratory irritation.

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Exposure routes : Inhalation

Assessment : May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Remarks : No data available

Repeated dose toxicity

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Species : Rat

NOAEL : 4,000 mg/kg LOAEL : 8,000 mg/kg

Application Route : Oral Exposure time : 10 d

Aspiration toxicity

Not classified based on available information.

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Experience with human exposure

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

: Target Organs: respiratory tract irritation Inhalation

Further information

Product:

Remarks No data is available on the product itself.

SECTION 12: Ecological information

12.1 Toxicity

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 440 - 760 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna): 85 - 120 mg/l

Exposure time: 72 h

Toxicity to algae/aquatic

plants

: NOEC (Scenedesmus quadricauda (Green algae)): 425 mg/l

Exposure time: 8 Days Test Type: static test

Toxicity to microorganisms (Pseudomonas putida): > 10,000 mg/l

Exposure time: 16 h

12.2 Persistence and degradability

Product:

Biodegradability Result: Readily biodegradable.

Method: OECD 301D / EEC 84/449 C6

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Result: Readily biodegradable. Biodegradability

Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Bioaccumulation Remarks: No bioaccumulation is to be expected (log Pow <=

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4).

12.4 Mobility in soil

Components:

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate:

Mobility : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting poten-

tial

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.

Additional ecological infor-

mation

No data is available on the product itself.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Disposal together with normal waste is not allowed. Special

disposal required according to local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

 ADR
 : UN 3265

 IMDG
 : UN 3265

 IATA
 : UN 3265

14.2 UN proper shipping name

ADR : CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S.

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(citric acid)

IMDG : CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S.

(citric acid)

IATA : Corrosive liquid, acidic, organic, n.o.s.

(citric acid)

14.3 Transport hazard class(es)

 ADR
 : 8

 IMDG
 : 8

 IATA
 : 8

14.4 Packing group

ADR

Packing group : III
Classification Code : C3
Hazard Identification Number : 80
Labels : 8
Tunnel restriction code : (E)

IMDG

Packing group : III Labels : 8

EmS Code : F-A, S-B

IATA (Cargo)

Packing instruction (cargo : 856

aircraft)

Packing instruction (LQ) : Y841
Packing group : III
Labels : Corrosive

IATA (Passenger)

Packing instruction (passen- : 852

ger aircraft)

Packing instruction (LQ) : Y841
Packing group : III

Labels : Corrosive

14.5 Environmental hazards

ADR

Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

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SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the fol-

lowing entries should be considered:

Number on list 3

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

Not applicable

Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

EU) 2019/1021 as amended for Great Brit-

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

: Not applicable

Not applicable

UK REACH List of substances subject to authorisation

(Annex XIV)

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial

emissions (integrated pollution prevention and control)

Not applicable

The components of this product are reported in the following inventories:

TCSI : On the inventory, or in compliance with the inventory

TSCA : All substances listed as active on the TSCA inventory

AIIC : On the inventory, or in compliance with the inventory

DSL : All components of this product are on the Canadian DSL

ENCS : On the inventory, or in compliance with the inventory

ISHL : On the inventory, or in compliance with the inventory

KECI : On the inventory, or in compliance with the inventory

PICCS : On the inventory, or in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

NZIoC : Not in compliance with the inventory

TECI : On the inventory, or in compliance with the inventory

15.2 Chemical safety assessment

Exempt

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019



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SECTION 16: Other information

Full text of H-Statements

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

Full text of other abbreviations

Eye Irrit. : Eye irritation

STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture: Classification procedure:

Met. Corr. 1	H290	Based on product data or assessment
Eye Irrit. 2	H319	Calculation method
STOT SE 3	H335	Calculation method
STOT SE 3	H335	Calculation method

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.