

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended
by UK REACH Regulations SI 2019/758



MEtherm 55 *No Change Service!*

Version
03.00

Revision Date:
29.07.2023

Date of last issue: 18.01.2022

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

1.1 Product identifier

Trade name : MEtherm 55
Unique Formula Identifier (UFI) : 9X50-30EY-V000-G41J

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

Use of the Substance/Mixture : Decalcification agent

Recommended restrictions on use : Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Supplier : MELAG Medizintechnik GmbH & Co. KG
Geneststraße 6-10

10829 Berlin
Germany
Telephone: +4930-7579110
Telefax: +4930-75791199
MEtherm-OEM@melag.de
www.melag.com

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

E-mail address of person responsible for the SDS/Contact person : ChemicalCompliance@schuelke.com

1.4 Emergency telephone number

Emergency telephone number : Carechem 24 International: +44 1235 239670

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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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 GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature

:

Solution of the following substances with harmless additives.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)

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1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate	5949-29-1 201-069-1 - - - 01-2119457026-42-XXXX	Eye Irrit. 2; H319 STOT SE 3; H335 (Respiratory system)	>= 50 - < 70
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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.

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

- Hazardous combustion prod- : No hazardous combustion products are known

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5.3 Advice for firefighters

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

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

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

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 storage conditions : Keep away from heat. Keep container tightly closed. Recommended 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

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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, 2-hydroxy-, monohydrate	Fresh water	0.44 mg/l
	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 specifications 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 protection.

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : No personal respiratory protective equipment normally required.

Protective measures : Avoid contact with skin and eyes.

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)

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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/cm ³ (20 °C)
Solubility(ies) Water solubility	:	completely soluble (20 °C)
Partition coefficient: n-octanol/water	:	Not applicable
Viscosity Viscosity, dynamic	:	ca. 4 mPa*s Method: ISO 3219
Viscosity, kinematic	:	not determined
Explosive properties	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
9.2 Other information		
Flammability (liquids)	:	Does not sustain combustion.
Metal corrosion rate	:	> 6.25 mm/a Corrosive to metals Aluminium and Mild steel
Self-ignition	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

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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 administration) : LD50 intravenous (Rat): 725 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

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

Species : Rabbit

Result : Mild skin irritation

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

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Method : OECD Test Guideline 405
Result : Eye 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:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 0 - 5 mg/ plate
Method: Mutagenicity (Salmonella typhimurium - reverse mutation 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

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

Carcinogenicity

Not classified based on available information.

Components:

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

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

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Reproductive toxicity

Not classified based on available information.

Components:

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

Effects on foetal development : Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 2,500 mg/kg body weight

Reproductive toxicity - Assessment : No toxicity to reproduction

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.

Experience with human exposure

Components:

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

Inhalation : Target Organs: respiratory tract irritation

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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
Toxicity to daphnia and other aquatic invertebrates	: 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:

Biodegradability	: Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d Method: OECD Test Guideline 301B
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12.3 Bioaccumulative potential

Components:

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

Bioaccumulation	: Remarks: No bioaccumulation is to be expected (log Pow <= 4).
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12.4 Mobility in soil

Components:

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

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|| 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 potential : 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 information : 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 handling 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. (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)

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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 aircraft) : 856
Packing instruction (LQ) : Y841
Packing group : III
Labels : Corrosive

IATA (Passenger)
Packing instruction (passenger aircraft) : 852
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.

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 following entries should be considered:

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UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	: Number on list 3 : Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	: Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	: Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	: Not applicable
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

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
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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.