

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 55 *No Change Service!*

Version
03.01

Revision Date:
22.03.2024

Date of last issue: 29.07.2023

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 Sub-stance/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 : Emergency medical information: 8am-10pm (seven days)
contact National Poisons Information Centre,
Beaumont Hospital, Dublin 9 DOV2NO
+353 (0)1 8092166

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Corrosive to metals, Category 1

H290: May be corrosive to metals.

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Eye irritation, Category 2

H319: Causes serious eye 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)

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.

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 : Solution of the following substances with harmless additives.

Components

Chemical name	CAS-No. EC-No.	Classification	Concentration (% w/w)
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	Index-No. Registration number		
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) STOT SE 3; H335 (Respiratory system)	>= 30 - < 50

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.

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5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : 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

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) according to Regulation (EC) No. 1907/2006:

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

Physical state : liquid

Colour : colourless

Odour : nearly odourless

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Odour Threshold	:	not determined
Melting point/freezing point	:	ca. 0 °C
Decomposition temperature		Not applicable
Boiling point/boiling range	:	ca. 100 °C
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
pH	:	2 (20 °C) Concentration: 100 %
Viscosity		
Viscosity, dynamic	:	ca. 4 mPa*s Method: ISO 3219
Viscosity, kinematic	:	not determined
Solubility(ies)		
Water solubility	:	(20 °C) completely soluble
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	ca. 25 hPa (20 °C)
Density	:	ca. 1.17 g/cm ³ (20 °C)
Relative vapour density	:	No data available

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9.2 Other information

Explosives	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Flammability (liquids)	:	Does not sustain combustion.
Metal corrosion rate	:	> 6.25 mm/a Corrosive to metals Aluminium and Mild steel
Evaporation rate	:	No data available

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 hazard classes as defined in Regulation (EC) No 1272/2008

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

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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
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

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		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
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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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

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.

Experience with human exposure

Components:

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

Inhalation : Target Organs: respiratory tract irritation

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

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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

12.3 Bioaccumulative potential

Components:

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

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

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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12.7 Other adverse effects

Product:

Additional ecological information : No data is available on the product itself.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of the product according to the defined EWC (European Waste Code) No.

Contaminated packaging : Take empty packaging to the recycling plant.

Waste key for the unused product : EWC 070601*

Waste key for the unused product(Group) : Waste material of HZVA from fats, lubricants, soaps, detergents, disinfectants and personal protection products.

SECTION 14: Transport information

14.1 UN number or ID 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)

	Class	Subsidiary risks
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)

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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.
For personal protection see section 8.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	: Conditions of restriction for the following entries should be considered: Number on list 75, 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	: Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	: Not applicable
Regulation (EC) No 649/2012 of the European Parliament	: Not applicable

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ment and the Council concerning the export and import
of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable
(Annex XIV)

Seveso III: Directive 2012/18/EU of the Euro- Not applicable
pean Parliament and of the Council on the
control of major-accident hazards involving
dangerous substances.

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial
emissions (integrated pollution prevention and control)
Not applicable

Other regulations:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU)
2020/878

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

No Chemical Safety Assessment has been carried out for this mixture.

SECTION 16: Other information

Full text of H-Statements

H319 : Causes serious eye irritation.

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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; AIIIC - 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

Met. Corr. 1	H290
Eye Irrit. 2	H319
STOT SE 3	H335

Classification procedure:

Based on product data or assessment
Calculation method
Calculation method

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

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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.