

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

MELAG
competence in hygiene

MEtherm 55 *No Change Service!*

Version
01.00

Revision Date:
08.03.2017

Date of last issue: -
Date of first issue: 08.03.2017

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

1.1 Product identifier

Trade name : MEtherm 55

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

Use of the Sub-
stance/Mixture : Additive

Recommended restrictions
on use : Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Manufacturer/ Supplier : MELAG Medizintechnik oHG
Geneststraße 6-10

10829 Berlin
Germany
Telephone: +4930-7579110
Telefax: +4930-757901199
info@melag.de
www.melag.de

E-mail address of person
responsible for the
SDS/Contact person : Safety Coordinator:
+49(0)30 /335 055 33

1.4 Emergency telephone number

Emergency telephone num-
ber : UK Poisons Emergency number: 0870 600 6266

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Corrosive to metals, Category 1
Eye irritation, Category 2

H290: May be corrosive to metals.
H319: Causes serious eye 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.

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

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P337+P313

present and easy to do. Continue rinsing.
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.

No special risks known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

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

Hazardous components

| Chemical name | Index-Number CAS-No. EC-No. Registration number | Classification | Concentration (% w/w) |
|-------------------------|--|--------------------|--------------------------|
| Citric acid monohydrate | - - - 5949-29-1 201-069-1 | Eye Irrit. 2; H319 | 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.
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 : Do NOT induce vomiting. Drink water as a precaution. If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Treat symptomatically.,

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 : High volume water jet

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5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

Specific risk from the substance or the product itself, its combustion products or evolved gases : Carbon dioxide (CO₂), Carbon monoxide

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

SECTION 8: Exposure controls/personal protection

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8.1 Control parameters

none

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

| Substance name | Environmental Compartment | Value |
|-------------------------|---------------------------|-------------|
| Citric acid 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 protection : Safety glasses with side-shields conforming to EN166

Hand protection
Directive : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC 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.

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 : ca. 2, 20 °C, concentrate
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
Flammability (solid, gas) : Not applicable
Upper explosion limit : Not applicable
Lower explosion limit : Not applicable

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| | |
|--|--------------------------------------|
| 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 | : in all proportions , 20 °C |
| Partition coefficient: n-octanol/water | : Not applicable |
| Auto-ignition temperature | : No data available |
| Viscosity | |
| Viscosity, dynamic | : ca. 4 mPa*s, ISO 3219 |
| Explosive properties | : No data available |
| Oxidizing properties | : Not applicable |

9.2 Other information

Corrosive in contact with metals : > 6,25 mm/a, Corrosive to metals, Aluminium, 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

None reasonably foreseeable.

10.4 Conditions to avoid

Protect from frost, heat and sunlight.

10.5 Incompatible materials

Metals,

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

| | |
|---------------------------|---|
| Acute oral toxicity | : Acute toxicity estimate: > 10.000 mg/kg |
| Acute inhalation toxicity | : Acute toxicity estimate: > 50 mg/l |
| Acute dermal toxicity | : Acute toxicity estimate: > 5.000 mg/kg |

Skin corrosion/irritation

Components:

Citric acid monohydrate:

Rabbit, Mild skin irritation, Based on available data, the classification criteria are not met.

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Serious eye damage/eye irritation

Product:

Causes serious eye irritation., Calculation method

Respiratory or skin sensitisation

Components:

Citric acid monohydrate:

Does not cause skin sensitisation.OECD Test Guideline 406

Germ cell mutagenicity

Components:

Citric acid monohydrate:

Germ cell mutagenicity- Assessment : not mutagenic

Carcinogenicity

Components:

Citric acid monohydrate:

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

Reproductive toxicity

Components:

Citric acid monohydrate:

Effects on fertility : Rat, Oral, NOAEL: 2.500 mg/kg
Reproductive toxicity - Assessment : No toxicity to reproduction

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

Components:

Citric acid monohydrate:

Rat, NOAEL: 1.200 mg/kg, Oral

Aspiration toxicity

No data available

Further information

Product:

No data is available on the product itself.

SECTION 12: Ecological information

12.1 Toxicity

Components:

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Citric acid monohydrate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 440 - 760 mg/l, 96 h
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna): 85 - 120 mg/l, 72 h
Toxicity to algae : IC5 (Scenedesmus quadricauda (Green algae)): 640 mg/l

12.2 Persistence and degradability

Product:

Biodegradability : Readily biodegradable., OECD 301D / EEC 84/449 C6
Chemical Oxygen Demand (COD) : 2.900 mg/l ,1 % solution

Components:

Citric acid monohydrate:

Biodegradability : Readily biodegradable., OECD Test Guideline 301B

12.3 Bioaccumulative potential

Components:

Citric acid monohydrate:

Bioaccumulation : No bioaccumulation is to be expected (log Pow <= 4).

12.4 Mobility in soil

Components:

Citric acid monohydrate:

Mobility : 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:

Additional ecological information : none

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 : European waste catalog (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

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14.1 UN number

IMDG : UN 3265

IATA : UN 3265

14.2 UN proper shipping name

IMDG : CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S.
(Citric acid monohydrate)

IATA : Corrosive liquid, acidic, organic, n.o.s.
(Citric acid monohydrate)

14.3 Transport hazard class(es)

IMDG : 8

IATA : 8

14.4 Packing group

IMDG
Packing group : III
Labels : 8
EmS Code : F-A, S-B

IATA
Packing instruction (cargo aircraft) : 856
Packing group : III
Labels : Corrosive

14.5 Environmental hazards

IMDG
Marine pollutant : no

14.6 Special precautions for user

For personal protection see section 8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving : Not applicable

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dangerous substances.

Volatile organic compounds : none, Directive 2010/75/EC on the limitation of emissions of volatile organic compounds

Other regulations : Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values.

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of H-Statements

H319 : Causes serious eye irritation.

Full text of other abbreviations

Eye Irrit. : Eye irritation

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; AICS - Australian Inventory of Chemical Substances; 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; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

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Further information

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) No. 1272/2008

Met. Corr. 1, H290 : Calculation method
Eye Irrit. 2, H319 : Calculation method

|| Changes compared with the previous edition!!!

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