

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

Revision Date:
22.03.2021

Date of last issue: 08.09.2020

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 56
Unique Formula Identifier (UFI) : 9P50-K0CS-X00H-G39C

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: +4930-757901199
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 : Safety Coordinator:
+49(0)30 /335 055 33

1.4 Emergency telephone number

Emergency telephone number : 031 8379964

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.

Skin corrosion, Sub-category 1B H314: Causes severe skin burns and eye damage.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 No Change Service!

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Serious eye damage, Category 1

H318: Causes serious eye damage.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard Statements : H290 May be corrosive to metals.
H314 Causes severe skin burns and eye damage.

Precautionary Statements : **Prevention:**
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

phosphoric acid

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 hazards to be specially mentioned.

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.	Classification	Concentration (% w/w)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

Revision Date:
22.03.2021

Date of last issue: 08.09.2020

Date of first issue: 08.03.2017

	Registration number		
phosphoric acid	7664-38-2 231-633-2 015-011-00-6 01-2119485924-24-XXXX	Met. Corr. 1; H290 Skin Corr. 1B; H314 Eye Dam. 1; H318	>= 50 - < 70

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 symptoms persist, call a physician.
- In case of skin contact : Wash off immediately with plenty of water for at least 15 minutes.
Consult a physician.
- In case of eye contact : In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Obtain medical attention.
- 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 : corrosive effects

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

- Specific hazards during fire- : Gives off hydrogen by reaction with metals.

according to Regulation (EC) No. 1907/2006



Date of first issue: 08.03.2017

Combustion produces caustic fumes.

5.3 Advice for firefighters

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

6.1 Personal precautions, protective equipment and emergency procedures

6.2 Environmental precautions

6.3 Methods and material for containment and cleaning up

6.4 Reference to other sections

see Section 8 + 13

7.1 Precautions for safe handling

Hygiene measures : Keep away from food and drink.

7.2 Conditions for safe storage, including any incompatibilities

Advice on common storage : Do not store together with alkalis.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

Revision Date:
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7.3 Specific end use(s)

Specific use(s) : none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
phosphoric acid	7664-38-2	TWA	1 mg/m ³	2000/39/EC
	Further information: Indicative			
		STEL	2 mg/m ³	2000/39/EC
	Further information: Indicative			
		OELV - 8 hrs (TWA)	1 mg/m ³	IE OEL
	Further information: Indicative Occupational Exposure Limit Value			
		OELV - 15 min (STEL)	2 mg/m ³	IE OEL
	Further information: Indicative Occupational Exposure Limit Value			

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
phosphoric acid	Workers	Inhalation	Long-term local effects	2 mg/m ³
	Workers	Inhalation	Long-term local effects	1 mg/m ³
	Workers	Inhalation	Long-term systemic effects	10.7 mg/m ³

8.2 Exposure controls

Engineering measures

Ensure that eyewash stations and safety showers are close to the workstation location.

Personal protective equipment

Eye protection : Face-shield

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

Revision Date:
22.03.2021

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Skin and body protection	:	Work uniform or laboratory coat. Chemical resistant apron
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	:	1.2 (20 °C) Concentration: 100 %
Melting point/freezing point	:	< -5 °C
Decomposition temperature	:	No data available
Boiling point/boiling range	:	ca. 100 °C
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Vapour pressure	:	ca. 25 hPa (20 °C)
Vapour density	:	No data available
Relative density	:	ca. 1.43 g/cm ³ (20 °C)
Solubility(ies) Water solubility	:	completely soluble (20 °C)
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

Revision Date:
22.03.2021

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Viscosity
Viscosity, dynamic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

9.2 Other information

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 : Reaction with alkalis(caustic liquors).

10.4 Conditions to avoid

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

10.5 Incompatible materials

Materials to avoid : Incompatible with strong bases and oxidizing agents.

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Components:

phosphoric acid:

Acute oral toxicity : LD50: 2,600 mg/kg
Method: Expert judgement

Acute dermal toxicity : LD50 (Rabbit): 2,740 mg/kg

Skin corrosion/irritation

Product:

Remarks : Causes severe skin burns and eye damage.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

Revision Date:
22.03.2021

Date of last issue: 08.09.2020
Date of first issue: 08.03.2017

Components:

phosphoric acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Corrosive after 3 minutes to 1 hour of exposure

Serious eye damage/eye irritation

Product:

Remarks : Causes serious eye damage.

Components:

phosphoric acid:

Species : Rabbit
Result : Irreversible effects on the eye

Respiratory or skin sensitisation

Components:

phosphoric acid:

Result : Does not cause skin sensitisation.
Remarks : largely based on human evidence

Germ cell mutagenicity

Components:

phosphoric acid:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

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

Carcinogenicity

Components:

phosphoric acid:

Carcinogenicity - Assessment : No data available

Reproductive toxicity

Components:

phosphoric acid:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

Revision Date:
22.03.2021

Date of last issue: 08.09.2020
Date of first issue: 08.03.2017

- Effects on fertility : Species: Rat, male and female
Application Route: Oral
General Toxicity F1: NOAEL: ≥ 500 mg/kg bw/day
- Effects on foetal development : Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: ≥ 410 mg/kg bw/day
Developmental Toxicity: NOAEL F1: ≥ 410 mg/kg bw/day
Method: OECD Test Guideline 414
Result: Animal testing did not show any effects on fertility.
- Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.
Animal testing did not show any effects on foetal development.

STOT - single exposure

Components:

phosphoric acid:

- Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Components:

phosphoric acid:

- Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

phosphoric acid:

- Species : Rat
NOAEL : 250 mg/kg
Application Route : Oral
Exposure time : 90-day
Method : OECD Test Guideline 422

Aspiration toxicity

No data available

Further information

Product:

- Remarks : No data is available on the product itself.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

Revision Date:
22.03.2021

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Date of first issue: 08.03.2017

SECTION 12: Ecological information

12.1 Toxicity

Components:

phosphoric acid:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 3 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : (Daphnia magna (Water flea)): > 100 mg/l
aquatic invertebrates Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
plants Exposure time: 72 h
Method: OECD Test Guideline 201

Ecotoxicology Assessment

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

12.2 Persistence and degradability

Components:

phosphoric acid:

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

Components:

phosphoric acid:

Bioaccumulation : Remarks: Not relevant

12.4 Mobility in soil

Components:

phosphoric acid:

Mobility : Medium: Water
Remarks: soluble

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..

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 *No Change Service!*

Version
02.02

Revision Date:
22.03.2021

Date of last issue: 08.09.2020
Date of first issue: 08.03.2017

12.6 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 : 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

14.1 UN number

ADR : UN 1805

IMDG : UN 1805

IATA : UN 1805

14.2 UN proper shipping name

ADR : PHOSPHORIC ACID SOLUTION

IMDG : PHOSPHORIC ACID SOLUTION

IATA : Phosphoric acid, solution

14.3 Transport hazard class(es)

ADR : 8

IMDG : 8

IATA : 8

14.4 Packing group

ADR

Packing group : III

Classification Code : C1

Hazard Identification Number : 80

Labels : 8

Tunnel restriction code : (E)

IMDG

Packing group : III

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

Revision Date:
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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 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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

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

REACH - List of substances subject to authorisation (Annex XIV) : 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 and the Council concerning the export and import of dangerous chemicals : Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

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Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

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

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.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of H-Statements

H290 : May be corrosive to metals.
H314 : Causes severe skin burns and eye damage.
H318 : Causes serious eye damage.

Full text of other abbreviations

Eye Dam. : Serious eye damage
Met. Corr. : Corrosive to metals
Skin Corr. : Skin corrosion
2000/39/EC : Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
2000/39/EC / TWA : Limit Value - eight hours
2000/39/EC / STEL : Short term exposure limit
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference period)

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 -

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



MEtherm 56 **No Change Service!**

Version
02.02

Revision Date:
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Date of last issue: 08.09.2020

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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; 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
Skin Corr. 1B	H314
Eye Dam. 1	H318

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 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.