

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Metherm® 61 **No Change Service!**

Version
01.00

Revision Date:
05.12.2018

Date of last issue: -
Date of first issue: 05.12.2018

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

1.1 Product identifier

Trade name : Metherm® 61

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)

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

Precautionary statements : P280 Wear eye protection/ face protection.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with wa-

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ter for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/attention.

Further information : The product is classified in accordance with Annex I (2.6.4.5) to Regulation (EC) 1272/2008.

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.

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---|---|--|--------------------------|
| Propan-2-ol | 67-63-0 200-661-7 603-117-00-0 01-2119457558-25-XXXX | Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 | 5- 15 |
| Alcohol, C13-C15 branched and linear, butoxylated ethoxy- | 111905-53-4 Polymer --- --- | Acute Tox. 4; H302 Eye Irrit. 2; H319 Aquatic Chronic 3; H412 | 5- 15 |
| Alcohols, C9-11-iso, C10-rich, ethoxylated | 78330-20-8 Polymer --- --- | Acute Tox. 4; H302 Eye Dam. 1; H318 | 1 - 5 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : If symptoms persist, call a physician.

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

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- In case of skin contact : Wash off immediately with plenty of water.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- If swallowed : Obtain medical attention.

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 : Do not use a solid water stream as it may scatter and spread fire.

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 : No special precautions required.

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).

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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 : Prepare the working solution as given on the label(s) and/or the user instructions.

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.

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

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|-------------|---------|-------------------------------|------------------------------------|---|
| Propan-2-ol | 67-63-0 | Permissible exposure limit | 400 ppm 999 mg/m ³ | United Kingdom. Workplace Exposure Limits (EH40/2005): Table 1: |
| | | Short term exposure limit | 500 ppm 1,250 mg/m ³ | HSE |

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

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|---------|-----------------|--------------------------------------|-----------------------|
| Propan-2-ol | Workers | Skin contact | Long-term exposure, Systemic effects | 888 mg/kg |
| | Workers | Inhalation | Long-term exposure, Systemic effects | 500 mg/m ³ |

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

| Substance name | Environmental Compartment | Value |
|----------------|---|----------------|
| Propan-2-ol | Fresh water | 140.9 mg/l |
| | Marine water | 140.9 mg/l |
| | Fresh water sediment | 552 mg/kg |
| | Marine sediment | 552 mg/kg |
| | Soil | 28 mg/kg |
| | Intermittent use/release | 140.9 mg/l |
| | Effects on waste water treatment plants | 2251 mg/l |
| | Oral | 160 mg/kg food |

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 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.

Respiratory protection : No personal respiratory protective equipment normally required.

Protective measures : Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid

Colour : colourless

Odour : alcohol-like

Odour Threshold : not determined

pH : ca. 7 (20 °C)

Melting point/freezing point : <-5°C

Decomposition temperature : No data available

Boiling point/boiling range : ca. 80 °C

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| | | |
|--|---|--------------------------------------|
| Flash point | : | 37 °C Method: DIN 51755 Part 1 |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | ca. 35 hPa (20 °C) |
| Vapour density | : | No data available |
| Relative density | : | ca. 0.99 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 | : | No data available |
| Flow time | : | < 15 s at 20 °C Method: DIN 53211 |
| Explosive properties | : | No data available |
| Oxidizing properties | : | No data available |

9.2 Other information

Flammability (liquids) : Does not sustain combustion.

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

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

10.5 Incompatible materials

Materials to avoid : Never mix concentrates directly.

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: > 5,000 mg/kg
Acute inhalation toxicity : Acute toxicity estimate: > 50 mg/l
Acute dermal toxicity : Acute toxicity estimate: > 15,000 mg/kg

Components:

Propan-2-ol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): 39 mg/l
Exposure time: 4 h
Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Acute oral toxicity : LD50 (Rat): > 300 - 2,000 mg/kg
Assessment: Harmful if swallowed.
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Acute oral toxicity : LD50 (Rat): 500 - 2,000 mg/kg
Method: Calculated value
Remarks: Harmful if swallowed.
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available

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Skin corrosion/irritation

Components:

Propan-2-ol:

Result : No skin irritation

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Mild skin irritation

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Product:

Assessment : Causes serious eye irritation.
Method : Calculation method

Components:

Propan-2-ol:

Result : Causes serious eye irritation.

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Species : Rabbit
Assessment : Causes serious eye irritation.
Method : OECD Test Guideline 405

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Species : Rabbit
Method : OECD Test Guideline 405
Result : May cause irreversible eye damage.

Respiratory or skin sensitisation

Components:

Propan-2-ol:

Test Type : Buehler Test
Species : Guinea pig
Result : Did not cause sensitisation on laboratory animals.

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Remarks : No data available

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Alcohols, C9-11-iso, C10-rich, ethoxylated:

Remarks : No data available

Germ cell mutagenicity

Components:

Propan-2-ol:

Genotoxicity in vitro : Test Type: Ames test
Method: Mutagenicity (Escherichia coli - reverse mutation assay)
Result: Non mutagenic

Genotoxicity in vivo : Species: Mouse
Method: Mutagenicity (micronucleus test)
Remarks: Non mutagenic

Germ cell mutagenicity- As- : Not mutagenic in Ames Test
sessment

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Germ cell mutagenicity- As- : No data available
sessment

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Germ cell mutagenicity- As- : No data available
sessment

Carcinogenicity

Components:

Propan-2-ol:

Carcinogenicity - Assess- : Based on available data, the classification criteria are not met.
ment

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Carcinogenicity - Assess- : No data available
ment

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Carcinogenicity - Assess- : No data available
ment

Reproductive toxicity

Components:

Propan-2-ol:

Effects on foetal develop- : Species: Rat
ment Application Route: Oral

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General Toxicity Maternal: NOAEL: 400 mg/kg body weight

Reproductive toxicity - Assessment : Based on available data, the classification criteria are not met.

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Reproductive toxicity - Assessment : No data available

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Reproductive toxicity - Assessment : No data available

STOT - single exposure

Components: Propan-

2-ol:

Assessment : May cause drowsiness or dizziness.

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Remarks : No data available

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Remarks : No data available

STOT - repeated exposure

Components:

Propan-2-ol:

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

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Remarks : Not classified due to data which are conclusive although insufficient for classification.

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Remarks : No data available

Aspiration toxicity

No data available

Further information

Product:

Remarks : No data is available on the product itself.

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SECTION 12: Ecological information

12.1 Toxicity

Components:

Propan-2-ol:

Toxicity to fish : LC50 (Leuciscus idus): > 100 mg/l
Exposure time: 48 h
Test Type: static test

Toxicity to daphnia and other : EC50 (Daphnia magna): > 100 mg/l
aquatic invertebrates Exposure time: 48 h
Test Type: static test

Toxicity to algae : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Toxicity to fish : LC50 (Leuciscus idus): 1 - 10 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna): > 1 - 10 mg/l
aquatic invertebrates Exposure time: 48 h
Test Type: semi-static test

Toxicity to algae : Remarks: No data available

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Toxicity to fish : LC50 (Leuciscus idus): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 : > 100 mg/l
aquatic invertebrates Exposure time: 48 h

Toxicity to algae : EC50 : > 100 mg/l
Exposure time: 72 h

12.2 Persistence and degradability

Components:

Propan-2-ol:

Biodegradability : Result: Readily biodegradable.

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Biodegradability : Result: Readily biodegradable.
Method: OECD Test Guideline 301F

Alcohols, C9-11-iso, C10-rich, ethoxylated:

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Biodegradability : Result: Readily biodegradable, according to appropriate OECD test.

12.3 Bioaccumulative potential

Components:

Propan-2-ol:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow ≤ 4).

Partition coefficient: n-octanol/water : log Pow: 0.05 (20 °C)
Method: OECD Test Guideline 107

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Bioaccumulation : Remarks: Accumulation in aquatic organisms is unlikely.

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Bioaccumulation : Remarks: According to experience not expected

12.4 Mobility in soil

Components:

Propan-2-ol:

Mobility : Remarks: Mobile in soils

Alcohol, C13-C15 branched and linear, butoxylated ethoxy-:

Mobility : Remarks: Substance does not evaporate from water surface into the atmosphere., Adsorption to solid soil phase is possible.

Alcohols, C9-11-iso, C10-rich, ethoxylated:

Mobility : Remarks: Adsorbs on soil.

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 : No data is available on the product itself.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

- | | | |
|---|---|--|
| Product | : | Dispose of the product according to the defined EWC (Euro-pean 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

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

- | | | |
|---------|---|---|
| Remarks | : | Not classified as supporting combustion according to the transport 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 mix-ture

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

| | | |
|---|---|----------------|
| Regulation (EC) No 850/2004 on persistent organic pol-lutants | : | Not applicable |
|---|---|----------------|

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

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Not applicable

Volatile organic compounds : Volatile organic compounds (VOC) content: 10 %
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

H225 : Highly flammable liquid and vapour.
H302 : Harmful if swallowed.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H336 : May cause drowsiness or dizziness.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
STOT SE : Specific target organ toxicity - single exposure

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

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Further information

Eye Irrit. 2, H319 : Calculation method

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

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