Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Issue date: 7/25/2022 Revision date: 7/25/2022 Supersedes: 5/31/2021 Version: 3.0

SDS No: 13129-0016



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

1.1. Product identifier

Product form : Mixture
Product name : Labomat SPM

UFI : WWK0-H0MQ-S00U-CE21

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Instrument cleaner

Medical devices

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Laboratorium Dr. Deppe GmbH

Hooghe Weg 35 47906 Kempen Germany

T +49 2152 55650 - F +49 2152 50849 sdb@drdeppe.de - www.drdeppe.de

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

1.4. Emergency telephone number

Emergency number : INTERNATIONAL: +49 6132 84463, GBK GmbH (24 h - 7 d/w - 365 d/a)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317
Specific target organ toxicity – Repeated exposure, Category 2 H373
Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause damage to organs through prolonged or repeated exposure. May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :





Signal word (CLP) : Warning

Contains : ethylene glycol, reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-

isothiazol-3-one (3:1)

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.

H373 - May cause damage to organs (kidneys) through prolonged or repeated exposure

(oral).

H412 - Harmful to aquatic life with long lasting effects.

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Precautionary statements (CLP) : P273 - Avoid release to the environment.

P280 - Wear protective gloves.

P314 - Get medical advice/attention if you feel unwell.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P261 - Avoid breathing mist, spray, vapours.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
ethylene glycol Substance with a Community workplace exposure limit	CAS-No.: 107-21-1 EC-No.: 203-473-3 EC Index-No.: 603-027-00-1 REACH-no: 01-2119456816- 28	≥ 20 – < 25	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) STOT RE 2, H373
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3- one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC-No.: 911-418-6 EC Index-No.: 613-167-00-5 REACH-no: 01-2120764691- 48	≥ 0.0015 - < 0.01	Acute Tox. 2 (Inhalation), H330 (ATE=0.05 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=50 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

Specific concentration limits:				
Name	Product identifier	Specific concentration limits		
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC-No.: 911-418-6 EC Index-No.: 613-167-00-5 REACH-no: 01-2120764691-	($0.0015 \le C \le 100$) Skin Sens. 1A, H317 ($0.06 \le C < 0.6$) Eye Irrit. 2, H319 ($0.06 \le C < 0.6$) Skin Irrit. 2, H315 ($0.6 \le C \le 100$) Eye Dam. 1, H318 ($0.6 \le C \le 100$) Skin Corr. 1C, H314		

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

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First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash

occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact : May cause an allergic skin reaction.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact

with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Do not breathe

dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes. Wear personal

protective equipment.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash

contaminated clothing before reuse. Do not eat, drink or smoke when using this product.

Always wash hands after handling the product.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

See Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

ethylene glycol (107-21-1)		
EU - Indicative Occupational Exposure Limit (IOEL)		
Local name	Ethylene glycol	
IOEL TWA	52 mg/m³	
IOEL TWA [ppm]	20 ppm	
IOEL STEL	104 mg/m³	
IOEL STEL [ppm]	40 ppm	
Remark	Skin	
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC	

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Protective goggles (EN 166)

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

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Hand protection:

Chemically resistant protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid Colour : yellowish Appearance : Clear Odour : Not available Odour threshold : Not available Melting point : Not available Freezing point : -13 °C : 100 °C Boiling point Flammability : Not applicable **Explosive limits** : Not available Lower explosive limit (LEL) Not available Upper explosive limit (UEL) : Not available Flash point : Not available Auto-ignition temperature : Not available Decomposition temperature : Not available : 6.6 - 7.3рΗ : Not available Viscosity, kinematic Solubility : Not available Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : 0.123 hPa : Not available Vapour pressure at 50 °C : 1.025 - 1.036 g/ml Density Relative density : Not available Relative vapour density at 20 °C : Not available Particle characteristics : Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

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10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

: Not classified Acute toxicity (oral) : Not classified Acute toxicity (dermal) Acute toxicity (inhalation) : Not classified

ethyle	ene gly	ycol ((107-21	I-1)
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ATE CLP (oral)

ATE CLP (dermal)

ATE CLP (dust,mist)

and the second s			
reaction mass of 5-chlor	o-2-methyl-2H-isothiazol-3-one	and 2-mathyl-2H-icathia	zal-2-and /2:1\ /55065-8/1-0\
reaction mass of s-cition	0-2-1116tily1-211-130tilla201-3-0116	e and z-inethyr-zhr-130thia	201-3-0116 (3.1) (33303-04-3)

500 mg/kg bodyweight

50 mg/kg bodyweight

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Α	TE CLP (oral)	100 mg/kg bodyweight	

0.05 mg/l/4h

ATE CLP (gases)	100 ppmv/4h
ATE CLP (vapours)	0.5 mg/l/4h

Skin corrosion/irritation : Not classified

pH: 6.6 - 7.3 : Not classified Serious eye damage/irritation pH: 6.6 - 7.3

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified Carcinogenicity : Not classified Reproductive toxicity : Not classified STOT-single exposure : Not classified

STOT-repeated exposure : May cause damage to organs (kidneys) through prolonged or repeated exposure (oral).

STOT-repeated exposure May cause damage to organs (kidneys) through prolonged or repeated exposure (Ingestion).

Aspiration hazard : Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects.

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Hazardous to the aquatic environment, short-term

(acute)

Hazardous to the aquatic environment, long-term

(chronic)

: Harmful to aquatic life with long lasting effects.

: Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID		
14.1. UN number or ID n	14.1. UN number or ID number					
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated		
14.2. UN proper shippin	g name					
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated		
14.3. Transport hazard o	14.3. Transport hazard class(es)					
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated		
14.4. Packing group	14.4. Packing group					
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated		
14.5. Environmental hazards						
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated		
No supplementary information available						

14.6. Special precautions for user

Overland transport

Not regulated

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Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

EU restriction list (REACH Annex XVII)				
Reference code	Applicable on	Entry title or description		
3(b)	Labomat SPM; ethylene glycol; reaction mass of 5-chloro-2-methyl-2H- isothiazol-3-one and 2- methyl-2H-isothiazol-3- one (3:1)	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10		
3(c)	Labomat SPM; reaction mass of 5-chloro-2- methyl-2H-isothiazol-3- one and 2-methyl-2H- isothiazol-3-one (3:1)	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1		

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Other information, restriction and prohibition regulations

: Medical devices as defined in Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on drug precursors)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
		Modified	

Abbreviations and acronyms:			
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		
ATE	Acute Toxicity Estimate		
BCF	Bioconcentration factor		
BLV	Biological limit value		
BOD	Biochemical oxygen demand (BOD)		
COD	Chemical oxygen demand (COD)		
DMEL	Derived Minimal Effect level		
DNEL	Derived-No Effect Level		
EC-No.	European Community number		
EC50	Median effective concentration		
EN	European Standard		
IARC	International Agency for Research on Cancer		
IATA	International Air Transport Association		
IMDG	International Maritime Dangerous Goods		
LC50	Median lethal concentration		
LD50	Median lethal dose		
LOAEL	Lowest Observed Adverse Effect Level		
NOAEC	No-Observed Adverse Effect Concentration		
NOAEL	No-Observed Adverse Effect Level		
NOEC	No-Observed Effect Concentration		
OECD	Organisation for Economic Co-operation and Development		
OEL	Occupational Exposure Limit		
PBT	Persistent Bioaccumulative Toxic		
PNEC	Predicted No-Effect Concentration		
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail		
SDS	Safety Data Sheet		
STP	Sewage treatment plant		
ThOD	Theoretical oxygen demand (ThOD)		
TLM	Median Tolerance Limit		
VOC	Volatile Organic Compounds		
CAS-No.	Chemical Abstract Service number		
N.O.S.	Not Otherwise Specified		

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Abbreviations and acronyms:			
vPvB	Very Persistent and Very Bioaccumulative		
ED	Endocrine disrupting properties		
DOT	Department of Transport		
TDG	Transportation of Dangerous Goods		
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006		
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals		
CAS	CAS (Chemical Abstracts Service) number		
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk		
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008		
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships		
ADG	Transport of Australian Dangerous Goods		

Other information

: Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

Full text of H- and EUH-statements:			
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2		
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2		
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3		
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4		
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1		
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1		
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3		
EUH071	Corrosive to the respiratory tract.		
Eye Dam. 1	Serious eye damage/eye irritation, Category 1		
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2		
H301	Toxic if swallowed.		
H302	Harmful if swallowed.		
H310	Fatal in contact with skin.		
H314	Causes severe skin burns and eye damage.		
H315	Causes skin irritation.		
H317	May cause an allergic skin reaction.		
H318	Causes serious eye damage.		
H319	Causes serious eye irritation.		
H330	Fatal if inhaled.		
H373	May cause damage to organs through prolonged or repeated exposure.		

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Full text of H- and EUH-statements:			
H400	Very toxic to aquatic life.		
H410	Very toxic to aquatic life with long lasting effects.		
H412	Harmful to aquatic life with long lasting effects.		
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C		
Skin Irrit. 2	Skin corrosion/irritation, Category 2		
Skin Sens. 1	Skin sensitisation, Category 1		
Skin Sens. 1A	Skin sensitisation, category 1A		
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2		

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:				
Skin Sens. 1	H317	Calculation method		
STOT RE 2	H373	Calculation method		
Aquatic Chronic 3	H412	Calculation method		

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.