



SAFETY DATA SHEET
according to Regulation (EC) No 1907/2006

Version: 1.0
Date of issue: 2024-05-13
Replaces version:

Trade name: AMH ELISA
Product number: DE6141

Usable for:

Cat.-No.:	Product:
DE6141	AMH ELISA

Single components where a safety data sheet is in attachment:

Kit Component	SDS Version
Enzyme Conjugate Standard 0 - 5 Control low & Control high Wash Solution, conc.	1.0_EN

Individual components not listed contain no hazardous substances in concentrations to be declared. A safety data sheet is not required for these components.

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IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: AMH ELISA
Product number: DE6141

*Kit Components: Enzyme Conjugate
Standard 0 – 5
Control low & Control high
Wash Solution, conc.*

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

Components of an *in-vitro* diagnostic device

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH	Phone: +49 (0)431 / 71922-0
Lise-Meitner-Str. 2	Fax: +49 (0)431 / 71922-55
24145 Kiel	E-Mail: info@demeditec.de
Germany	https://www.demeditec.de/

1.4 Emergency telephone number

+49 (0)431 / 71922-0
(Only available during the following office hours)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.2 Label elements

Hazard-determining ingredient of labelling: **CMIT/MIT (3:1); CAS-No: 55965-84-9** (reaction mass of 5-chloro-2- methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))



Hazard pictogram(s):

Signal word(s):

Warning

Hazard statement(s):

H317 - May cause an allergic skin reaction.
EUH071 - Corrosive to the respiratory tract

Precautionary statement(s):

P261 - Avoid breathing dust/fume/gas/mist/vapours/ spray.
P280 - Wear protective gloves.
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/ container to an approved waste disposal plant

2.3 Other hazards

Not applicable.



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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Substance name	CAS No. (EC No.) [Index No.] "REACH No."	Concentration in the mixture	Classification according to Regulation (EC) No 1272/2008 [CLP] (related to the concentrated form)		
			Hazard class / Hazard categories	Hazard-statement	Specific Conc. Limits, M-factors and ATE
reaction mass of 5-chloro-2- methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	55965-84-9 (---) [613-167-00-5]	0.01 %	Acute Tox. 2 Acute Tox. 2 Acute Tox. 3 Eye Irrit. 2 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H330 H310 H301 H319 H317 H400 H410	Eye Irrit. 2; H319: 0,06 % ≤ C < 0,6 % Skin Sens. 1A; H317: C ≥ 0,0015 % M = 10 M (long-term) = 1

Full text of H-phrases: see section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information

Show this safety data sheet to the doctor in attendance.

After inhalation

Remove to fresh air.

After contact with skin

Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.

After contact with eyes

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

After ingestion

Rinse mouth

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: Itching. Rashes. Hives.

4.3 Indication of any immediate medical attention and special treatment needed

Note to physicians: May cause sensitization in susceptible persons. Treat symptomatically.



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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Large Fire

CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media

Do not scatter spilled material with high pressure water streams.

5.2 Special hazards arising from the substance or mixture

Product is or contains a sensitizer. May cause sensitization by skin contact.

5.3 Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:

Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

For emergency responders:

Use personal protection recommended in Section 8.

6.2 Environmental precautions

See Section 12 for additional Ecological Information.

6.3 Methods and material for containment and cleaning up

For containment:

Prevent further leakage or spillage if safe to do so.

For cleaning up:

Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4 Reference to other sections

See section 8 for more information.

See section 13 for more information.



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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

General hygiene considerations

Handle in accordance with good laboratory hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Keep container tightly closed.
Keep cool. Protect from sunlight.
Keep/Store only in original container.
Never return spills in original containers for re-use.

Further information on storage condition

Storage temperature of 2 °C - 8 °C.

7.3 Specific end use(s)

Part of an immunoassay kit.
For professional laboratory use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Chemical Name	European Union	Austria	Belgium	Bulgaria	Croatia
2-methylisothiazol-3(2H)-one CAS # 2682-20-4	-	TWA: 0.05 mg/m ³	-	-	-
	France	Germany	Germany MAK	Greece	Hungary
	-	-	TWA: 0.2 mg/m ³ Peak: 0.4 mg/m ³	-	-
	Sweden	Switzerland	United Kingdom		
	-	TWA: 0.2 mg/m ³ STEL: 0.4 mg/m ³	-		

(TWA = time-weighted average, STEL = Short Term Exposure Limit)

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL)

No information available.



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Predicted No Effect Concentration (PNEC)

No information available.

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Wear safety glasses with side shields (or goggles).

Hand protection

Wear suitable gloves.

Skin and body protection

Wear suitable protective clothing.

Respiratory protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls

No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state: liquid
Appearance: clear
Colour: pale yellow
Odour: No information available.
Odour threshold: No information available

Property	Values	Remarks • Method
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air	None known	
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	None known
Flash point	No data available	
Autoignition temperature	No data available	None known
Decomposition temperature	None known	
pH	Neutral	
pH (as aqueous solution)	No data available	None known



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Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	Completely soluble	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapor pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapor density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2 Other information

Information with regard to physical hazard classes

Not applicable

Other safety characteristics

No information available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No information available.

10.2 Chemical stability

Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3 Possibility of hazardous reactions

None under normal processing.

10.4 Conditions to avoid

None known based on information supplied.

10.5 Incompatible materials

None known based on information supplied.

10.6 Hazardous decomposition products

None known based on information supplied.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Information on likely routes of exposure



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Product Information

Inhalation Specific test data for the substance or mixture is not available.
Eye contact Specific test data for the substance or mixture is not available.



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Skin contact May cause sensitization by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives.

Acute toxicity

Numerical measures of toxicity

No information available

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
2-methylisothiazol-3(2H)-one	232 - 249 mg/kg (Rat) = 120 mg/kg (Rat)	= 200 mg/kg (Rabbit)	= 0.11 mg/L (Rat) 4 h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization May cause sensitization by skin contact.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

No information available.

11.2.2 Other information

No information available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecotoxicity

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

Bioaccumulation



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12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
2-methylisothiazol-3(2H)-one	The substance is not PBT / vPvB

12.6 Endocrine disrupting properties

No information available.

12.7 Other adverse effects

No information available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation:

Must be recycled or disposed of according to the regulations. Waste has to be classified according to the European Waste Catalogue based on the identification of the waste generating source.

European waste catalogue:

16 05 06* laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals

Uncleaned packaging:

Recommendation:

Disposal must be made according to official regulations.

Packaging that cannot be cleaned are to be disposed of in the same manner as the product.

Recommended cleansing agent: Water; if necessary, with cleansing agents



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SECTION 14: TRANSPORT INFORMATION

	IATA	IMDG	RID	ADR
1.1 <u>UN number or ID number</u>	Not regulated	Not regulated	Not regulated	Not regulated
1.2 <u>UN Proper shipping name</u>	Not regulated	Not regulated	Not regulated	Not regulated
1.3 <u>Transport hazard class(es)</u>	Not regulated	Not regulated	Not regulated	Not regulated
1.4 <u>Packing group</u>	Not regulated	Not regulated	Not regulated	Not regulated
1.5 <u>Environmental hazards</u>	Not applicable	Not applicable	Not applicable	Not applicable
1.6 <u>Special precautions for user</u> Special Provisions	None	None	None	None
1.7 <u>Maritime transport in bulk according to IMO instruments</u>		Not applicable		

SECTION 15: REGULATORY INFORMATION

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

European Union

Take note of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

15.2 Chemical safety assessment

Not applicable.

SECTION 16: OTHER INFORMATION

Relevant H and EUH statements referred to under section 3

EUH071 - Corrosive to the respiratory tract

H330 - Fatal if inhaled.

H310 - Fatal in contact with skin.

H301 - Toxic if swallowed.

H317 - May cause an allergic skin reaction.

H410 - Very toxic to aquatic life with long lasting effects.

Abbreviations and acronyms

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

ATE: Acute toxicity estimate

BCF: Bio-concentration factor

CAS: Chemical Abstracts Service

CLP: Classification, labelling and Packaging

DMEL: Derived Minimal Effect Level



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DNEL: Derived No Effect Level
EC50: Effective Concentration 50%
EL50: Effect loading, 50%
EmS: Emergency Schedules
ErC50: Effective Concentration 50%, growth rate
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
IATA: International Air Transport Association
IBC: Intermediate Bulk Container
ICAO: International Civil Aviation Organization
IMDG: International Maritime Code for Dangerous Goods
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
LL50: Lethal loading, 50%
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
MFAG: Medical First Aid Guide
NOEC: No Observed Effect Concentration
PBT: persistent, bioaccumulative, toxic
PNEC: Predicted No Effect Concentration
REACH: Registration, Evaluation and Authorization of Chemicals
RID: Regulations concerning the international carriage of dangerous goods by rail
SVHC: Substance of Very High Concern
UN: United Nations
vPvB: very persistent, very bioaccumulative