

Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA

Date of creation / revision: 2019-03-08

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

1.1. Product identifier	
Trade name:	Aflatoxin M1 ELISA
Article Number:	DEAM1E01

Components:

- 0) Microtiter Plate
 1) Substrate Solution
 2) Antibody Solution
 3) Conjugate
 4) Washing Solution (10x Concentrate)
 5) Sample/ Standard Diluent
- 6) Aflatoxin M1 Standards
- 7) Stop Solution

Concerning safety the microtiter plate (0) is inoffensive and for this reason not part of this document. The mixtures 1 - 5, due to coincident categorization, are combined as a group and treated and dealt with below. The mixtures 6 (standards) and 7 (Stop Solution) are each treated in a separate safety data sheet below.

1.2. Application of the substance / the preparation

Enzyme immunoassay for the quantitative determination of M1 Aflatoxin in food.

1.3. Details of the supplier of the safety data sheet

editec Diagnostics GmbH
Veitner-Str. 2
5 Kiel
any
+49(0)431 / 71922-0
demeditec.de

1.4. Emergency telephone number

In case of further inquiry please contact the telephone number +49(0)431 / 71922-0 (technical service, business hours 8 a.m. to 4:30 p.m.).



Safety Data Sheet

According to 1907/2006/EC, Article 31 (REACH) According to 1272/2008/EC (GHS/CLP)

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2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or Directive 1999/45/EC: No classification applicable.

Classification according to Regulation (EC) No 1272/2008: The mixtures are not classified according to the CLP regulation.

Information concerning particular hazards for human and environment: The mixtures do not have to be labeled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest version.

Classification system: The mixtures are classified as non-hazardous according to the criteria of Directive 67/548/EEC and Directive 1999/45/EC or Regulation(EC) No 1272/2008.

2.2. Label elements Labeling according to Regulation (EC) No 1272/2008: Hazard pictograms: Signal word:	Void. Void. Void.
Hazard statements:	Void.

2.3. Other hazards

All chemicals are potentially dangerous. They should only be handled by specially trained personnel.**PBT:**Not applicable.**vPvB:**Not applicable.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures Description: Mixtures of substances with nonhazardous additions. Dangerous components: Void. Additional information: For the wording of the listed risk phrases refer to section 16.

4. FIRST AID MEASURES



4.1. Description of first aid measures

General information: First aider: Pay attention for self-protection!! Remove any clothing soiled by the product.

After Inhalation: Remove to fresh air. Consult a doctor in case of complaints.

After skin contact: Immediately rinse with water. If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing: Rinse out mouth and drink a glass of water. Do not induce vomiting. If there is any trouble seek medical help.

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

No further relevant information available.

4.3. Indication of any immediate medical attention and special treatment needed No further relevant information available.



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FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions. CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. **for safety reasons unsuitable extinguishing agents:** For this mixture no limitations of extinguishing agents are given.

5.2. Special hazards arising from the substance or mixture

Ambient fire may liberate hazardous vapours. In the event of fire development of hazardous combustion gases or vapours possible. In case of fire, the following gases can be released: Dioxid, carbon monoxide and carbon dioxide.

5.3. Important Advice for firefighters

Protective equipment: Wear self-contained respiratory protective device. Wear fully protective suit.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures Wear protective clothing.

6.2. Environmental precautions

Do not allow to enter sewers/ground water or penetrate the soil.

6.3. Methods and material for containment and cleaning up

Absorb with liquid binding material (sand diatomite, acid binders, universal binders, sawdust). Dispose of the material according to regulations.

6.4. Reference to other sections

See section 7 for information on safe handling. See section 8 for information on personal protection requirement. See section 13 for disposal information.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

No special precautions are necessary if used correctly. **Information about fire – and explosion protection:** No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Storage: Requirements to be met by storerooms and receptables: Store at a cool place. Information about storage in one common storage facility: Store away from foodstuffs. Further information about storage conditions: None. Recommended storage temperature: 2-8°C

7.2. Specific end use(s) No further relevant information available.



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Safety Data Sheet According to 1907/2006/EC, Article 31 (REACH)

According to 1272/2008/EC (GHS/CLP)

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EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional information about design of technical facilities: No further data: see item 7.

8.1. Control parameters

Ingredients with limit values that require monitoring at workplace: The mixtures do not contain any relevant quantities of materials with critical values that have to be monitored at the working place. Additional information: The lists valid during the making were used as basis.

8.2. Exposure controls

Personal protective equipment:

General protective and hygienic measures: Wash hands before breaks and at the end of work. Keep away from foodstuffs, beverages and feed. Avoid contact with the eyes and skin. Immediately remove all soiled and contaminated clothing.

Individual protection measures: Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier. **Respiratory protection:**



Protection of hands:



Not required.

Protective gloves - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. Nitrile, thickness: ≥ 0.11 mm. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material: Value of the permeation: Level ≥ 6. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed. **Body protection:**

Eye protection:



Protective work clothing.



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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

9.1. Information on basic physical and chemical properties Property Substrate So- Antibody Conjugate Washing Solu- Sample					
roporty	lution	Solution	Conjugato	tion (10x conc.)	Diluent
General information					2
Appearance:					
Form:				fluid	
Colour:	colourless	red	red	blue	red
Odour:	odourless	odourless	odourless	odourless	odourless
	No information				
Odour threshold:	available	available	available	available	available
pH-value at 25°C:	3,3 - 3,8	5,6-6,6	6,2 – 7,2	6,2 - 7,2	5,6 - 6,6
Change in condition:					
Melting point/	No information				
Melting range:	available	available	available	available	available
Boiling point/	No information				
Boiling range	available	100 °C	100 °C	100 °C	100 °C
	No information				
Flash point:	available	available	available	available	available
Flammability	No information				
(solid, gaseous)	available	available	available	available	available
Ignition temperature:					
Decomposition	No information				
temperature:	available	available	available	available	available
•	The mixture is				
Self-igniting:	not self-igniting				
	The mixture				
	does not pre-	does not pre-	does not pre-	does not present	does not pre-
Danger of explosion:	sent an explo-	sent an explo-	sent an explo-	an explosion	sent an explo-
	sion hazard	sion hazard	sion hazard	hazard	sion hazard
Explosion limits:					
	No information				
Lower:	available	available	available	available	available
	No information				
Upper:	available	available	available	available	available
A 111 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	No information				
Oxidizing properties	available	available	available	available	available
Vapour pressure	No information				
at 20 °C:	available	available	available	available	available
Density:					
	No information				
Density at 20 °C:	available	available	available	available	available
M	No information				
Vapour density:	available	available	available	available	available
	No information				
Evaporation rate:	available	available	available	available	available
Solubility in /	Fully miscible				
Miscibility with water:					
Partition coefficient	No information				
(n-Octanol/Water)	available	available	available	available	available
Viscosity:					
No information No information No information No information No information					
Dynamic:	available	available	available	available	available
	No information				
Kinematic:	available	available	available	available	available
	available	available	available	available	available

9.2. Other information

No further relevant information available.



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10. STABILITY AND REACTIVTY

10.1. Reactivity

No information available.

10.2. Chemical stability

Thermal decomposition / conditions to be avoided

No decomposition if used and stored according to specifications.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No dangerous decomposition products known. In case of fire see item 5.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

<u>Acute Toxicity:</u> LD/LC50 values relevant for classification: Quantitative data on the toxicity of the mixtures are not available.

Primary irrtant effect:

On the skin: No irritating effect known.

On the eyes: No irritating effect known.

After inhalation: No irritating effect known.

Sensitization: No sensitizing effects known.

CMR effects:

Germ cell mutagenicity: No information available.

Carcinogenicity: No information available.

Reproductive toxicity: No information available.

Aspiration hazard: No aspiration toxicity classification.

<u>Specific target organ toxicity – single exposure:</u> The mixtures are not classified as specific target organ toxicant, single exposure.

Specific target organ toxicity – repeated exposure: The mixtures are not classified as specific target organ toxicant, repeated exposure.

Additional toxicological information: We have no description of any toxicological symptoms.

11.2. Further information

The product should be handled with the care usual when dealing with chemicals.

Additional toxicological information: When used and handled according to specifications, the mixtures do not have any harmful effects to our experience and the information provided to us.



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Safety Data Sheet

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ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity: Quantitative data on the ecological effect of the mixtures are not available.

12.2. Persistence and degradability

No further relevant information available.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

No further relevant information available. <u>Ecotoxical effects:</u> Remark: Water hazard class 1 (German Regulation) (Self-assessment) – Do not allow to enter waters, sewers or soil.

12.5. Results of PBT and vPvB assessment

PBT: Not applicable. **vPvB:** Not applicable.

12.6. Other adverse effects

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Recommendation: This material and its container must be disposed of as hazardous waste. The disposal is regionally differently regulated, therefore the kind of disposal is to be inquired at the responsible authorities.

Uncleaned packaging:

Recommendation: Die Disposal according to official regulations.

Recommended Cleansing agents: Water, if necessary together with cleansing agents.



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TRANSPORT INFORMATION

14.1. UN-Number ADR, IMDG, IATA: Void.

14.2. UN proper shipping name ADR: Void. IMDG, IATA: Void

14.3. Transport hazard class(es) Void.

14.4. Packing group ADR, IMDG, IATA: Void.

14.5.Environmental hazards Marine pollutant: No.

14.6. Special precautions for user Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable. **UN "Model Regulation":** Void.

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substances or mixture <u>National regulations:</u>

Information about limitation of use: Employment restrictions concerning juveniles must be observed.

Waterhazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out.



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16. OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. **Relevant phrases:** Void.

Department issuing MSDS: Department R & D

Contact: 0049-431-71922-0, info@demeditec.de

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail) IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA) ICAO: International Civil Aviation Organization ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)

LD50: Letale Dose, 50 percent (Not relevant for classification)

LC50: Letale concentration, 50 percent (Not relevant for classification)



Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA – Aflatoxin M1 Standards

Date of creation / revision: 2019-03-08

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

1.1. Product identifier	
Trade name:	Aflatoxin M1 ELISA
Article Number:	DEAM1E01

Components:

- Diamination
 Microtiter Plate
 Substrate Solution
 Antibody Solution
 Conjugate
 Washing Solution (10x Concentrate)
 Sample/ Standard Diluent
 Aflatoxin M1 Standards
- 7) Stop Solution

Concerning safety the microtiter plate (0) is inoffensive and for this reason not part of this document. The mixtures 1 - 5, due to coincident categorization, are combined as a group and treated separately above. The mixture 7 (Stop solution) is also treated in a separate safety data sheet. The mixtures 6 (Aflatoxin M1 Standards) are the object of this safety data sheet and is dealt with below.

1.2. Application of the substance / the preparation Aflatoxin M1 Standards as part of the Aflatoxin M1 ELISA.

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier:	Demeditec Diagnostics GmbH Lise-Meitner-Str. 2
	24145 Kiel
	Germany
	Tel.: +49(0)431 / 71922-0
eMail-Address of the qualified person:	info@demeditec.de

1.4. Emergency telephone number

In case of further inquiry please contact the telephone number +49(0)431 / 71922-0 (technical service, business hours 8 a.m. to 4:30 p.m.).

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

- Classification according to Directive 67/548/EEC or Directive 1999/45/EC:
- T; Toxic

R23/24/25-39/23/24/25: Toxic by inhalation, in contact with skin and if swallowed. Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.

Classification according to Regulation (EC) No 1272/2008:

Acute Tox. 3 H301 Toxic if swallowed.

Acute Tox. 3 H311 Toxic in contact with skin.

Acute Tox. 3 H331 Toxic if inhaled.

STOT SE 1 H370 Causes damage to organs.

Special hazard notes for human and environment: The product has to be labeled due to the calculation procedure of the "General Classification guideline for preparation of the EU" in the latest valid version.

Classification system: The classification is according to the latest editions of the EU-lists, and extended by company and literature data.



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2.2. Label elements

Labeling according to Regulation (EC) No 1272/2008:

The product is classified and labelled according to the CLP regulation **Hazard pictograms**:



GHS06GHS08Signal word:Danger.Hazard statements:Toxic if swallowed, in contact with or if inhaled.H301+H311+H331Toxic if swallowed, in contact with or if inhaled.H370Causes damage to organs.

Precautionary statements:

P210	Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233	Keep container tightly closed.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P311	Call a POISON CENTER or doctor/physician.

2.3. Other hazards

All chemicals are potentially dangerous. They should only be handled by specially trained personnel..**PBT:**Not applicable.**vPvB:**Not applicable.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures Description: Mixture with methanol

Dangerous components:

CAS-No.:	67+	56-1	
Description:	÷.	nanol	
•			
EINECS:	200-6	659-6	
Index number:	603-00	1-00-X	
Elemental formula:	CF	1 ₄ O	
Molar Mass:	32,04		
Concentration in mixture:	~10	00%	
Classification according to Directive 67/548/EEC or Directive 1999/45/EC:		T R23/24/25- R39/23/24/25	
Classification according to Regulation (EC) No 1272/2008:		Acute Tox. 3 STOT SE 1 H301 + H311 + H331, H370	

Additional information: For the wording of the listed risk phrases refer to section 16.



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4. FIRST AID MEASURES



4.1. Description of first aid measures

General information: First aider: Pay attention for self-protection!! Remove any clothing soiled by the product. Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

After Inhalation: Remove to fresh air. I breathing is difficult, give oxygen. Seek medical advice immediately.

After skin contact: Immediately wash with water and soap and rinse thoroughly.

After massive or prolonged skin contact: Medical advice absolutely required!

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing: Remove to fresh air. Do not induce vomiting. Make victim drink ethanol (e.g. 1 drinking glass of a 40% alcoholic beverage). Call a doctor immediately.

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

- Irritations
- Dizziness
- Headache
- Impairment of vision
- Cramp
- Nausea
- Vomiting
- Unconsciousness

Hazards: Danger of impaired breathing. Blindness.

4.3. Indication of any immediate medical attention and special treatment needed No further relevant information available.

No further relevant information available

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions. CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. **for safety reasons unsuitable extinguishing agents:** For this mixture no limitations of extinguishing agents are given.

5.2. Special hazards arising from the substance or mixture

Ambient fire may liberate hazardous vapours. In the event of fire development of hazardous combustion gases or vapours possible. In case of fire, the following gases can be released: Carbon monoxide and carbon dioxide.

5.3. Important Advice for firefighters

Protective equipment: Wear self-contained respiratory protective device. Wear fully protective suit.



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6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective clothing. Keep away unprotected persons. Avoid eye or skin contact.

6.2. Environmental precautions

Do not allow to enter sewers/ground water or penetrate the soil.

6.3. Methods and material for containment and cleaning up

Absorb with liquid binding material (sand diatomite, acid binders, universal binders, sawdust). Dispose of the material according to regulations. Ensure adequate ventilation.

6.4. Reference to other sections

See section 7 for information on safe handling. See section 8 for information on personal protection requirement. See section 13 for disposal information.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace **Information about fire – and explosion protection:**



Keep ignition sources away - Do not smoke.

7.2. Conditions for safe storage, including any incompatibilities <u>Storage:</u>

Requirements to be met by storerooms and receptables: Store at a cool place. Information about storage in one common storage facility: Store away from foodstuffs. Further information about storage conditions: Keep container tighly closed. Recommended storage temperature: 2-8°C

7.2. Specific end use(s)

No further relevant information available.



Safety Data Sheet

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional information about design of technical facilities: No further data; see item 7.

8.1. Control parameters

Ingredients with limit values that require monitoring at workplace:	
67-56-1 Methanol	
AGW (Germany):	270 mg/m³, 200 mL/m³ 4 (II); DFG, EU, H, Y
IOELV (EU):	260 mg/m ³ , 200 mL/mL

DNEL values (Methanol):

workers				
long-term exposition – systemic effects:				
Dermal:	DNEL	40 mg/kg (Worker)		
Inhalativ:	DNEL	260 mg/m ³ (Worker)		
long-term exposition – loca	al effects:			
Inhalativ:	DNEL	260 mg/m ³ (Worker)		
short-term exposition – systemic effects:				
Dermal:	DNEL	40 mg/kg (Worker)		
Inhalativ:	DNEL	260 mg/m ³ (Worker)		
short-term exposition – local effects:				
Inhalativ:	DNEL	260 mg/m ³ (Worker)		

Consumer				
long-term exposition – systemic effects:				
Oral:	DNEL	8 mg/kg (Consumer)		
Dermal:	DNEL	8 mg/kg (Consumer)		
Inhalativ:	DNEL	50 mg/m ³ (Consumer)		
long-term exposition – loca	al effects:			
Inhalativ:	DNEL	50 mg/m ³ (Consumer)		
short-term exposition – sy	stemic effects:			
Oral:	DNEL	8 mg/kg (Consumer)		
Dermal:	DNEL	8 mg/kg (Consumer)		
Inhalativ:	DNEL	50 mg/m ³ (Consumer)		
short-term exposition – loc	al effects:			
Inhalativ:	DNEL	50 mg/m ³ (Consumer)		

PNEC values (Methanol):

	24 mg/kg (Soil)
	100 mg/L (Sewage treatment plant)
PNEC	15 mg/mL (Marine water)
	570 mg/kg (Fresh water sediment)
	154 mg/L (Fresh water)

Additional information: The lists valid during the making were used as basis.



According to 1272/2008/EC (GHS/CLP)

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8.2. Exposure controls

Personal protective equipment:

General protective and hygienic measures: Wash hands before breaks and at the end of work. Keep away from foodstuffs, beverages and feed. Avoid contact with the eyes and skin. Immediately remove all soiled and contaminated clothing. Do not inhale gases / fumes / aerosols. Clean skin thoroughly immediately after handling the product.

Individual protection measures: Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier. **Respiratory protection:**



Required when vapours/areosols are generated. Recommended filter type: Filter AX (colour code: brown). When selecting your respiratory unit: Consider the "Rules for the use of respiratory protection equipment" (BGR190)

Protection of hands:



Protective gloves – The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves: Butylcaoutchouc, thickness: $\geq 0,7$ mm. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material: Value for the permeation: Level ≥ 6 . The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:



Tightly sealed goggles.

Body protection:



Protective work clothing.



According to 1272/2008/EC (GHS/CLP)

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9. PHYSICAL AND CHEMICAL PROPERTIES

Property	Standards (in 100% Methanol)		
General information			
Appearance:			
Form: fluid			
Colour:	colourless		
Odour:	alcoholic		
Odour threshold:	2000 ppm (Methanol)		
pH-value at 25°C:	Not applicable		
Change in condition :			
Melting point/ Melting range:	No information available		
Boiling point/ Boiling range:	65°C (Methanol)		
Flash point:	No information available		
Flammability (solid, gaseous):	No information available		
Ignition temperature:	No information available		
Decomposition temperature:	No information available		
Self-igniting: The mixture is not self-igniting			
Danger of explosion:	No information available		
Explosion limits:			
Lower:	No information available		
Upper:	No information available		
Oxidizing properties:	No information available		
Vapour pressure at 20 °C:	23 hPa		
Density:			
Density at 20 °C:	0,99 g/cm ³		
Vapour density:	No information available		
Evaporation rate:	No information available		
Solubility in / Miscibility with water:	Fully miscible		
Partition coefficient (n-Octanol/Water):	No information available		
Viskosity:			
Dynamic:	No information available		
Kinematic:	No information available		
Solvent content:			
Organic solvents:	100%		
Water:	50%		

9.2. Other information

No further relevant information available.

10. STABILITY AND REACTIVTY

10.1. Reactivity

No information available.

10.2. Chemical stability

Thermal decomposition / conditions to be avoided

No decomposition if used and stored according to specifications.

10.3. Possibility of hazardous reactions

No hazardous reactions known.



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10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No dangerous decomposition products known. In case of fire see item 5.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity: LD/LC50 values relevant for classification:

67-56-1 Methanol

Oral:	LD0	143 mg/kg (human) (TOXNET)
Ulai.	LD50	5628 mg/kg (rat) (IUCLID)
dermal:	LD50	15800 mg/kg (rabbit) (TOXNET)
Inhalativ:	LC50/ 4h	85,3 mg/L (rat) (IUCLID)

Primary irrtant effect:

On the skin: Danger through skin adsorption. Repeated exposure may cause skin dryness or crackina.

On the eves: Slightly Irritant.

after inhalation: Absorption. Irritation symptoms in the respiratory tract.

Sensitization: No sensitizing effects known.

CMR effects:

Germ cell mutagenicity: No information available.

Carcinogenicity: No information available.

Reproductive toxicity: No information available.

Aspiration hazard: No aspiration toxicity classification.

Specific target organ toxicity - single exposure: The mixture is not classified as specific target organ toxicant, single exposure.

Specific target organ toxicity - repeated exposure: The mixture is not classified as specific target organ toxicant, repeated exposure.

Additional toxicological information (methanol):

After swallowing:

Nausea

Vomiting

Systemic effects:

Blood pressure drop Irritation Inebriation Headache Dizziness Impairment of vision Spasms Narcosis Coma Possibly respiratory arrest and heart attack. Symptoms may be delayed. Irreversible damage of the optical nerve. Blinding

Damage of liver and kidneys.

11.2. Further information

The product should be handled with the care ususal when dealing with chemicals.



Safety Data Sheet

According to 1907/2006/EC, Article 31 (REACH) According to 1272/2008/EC (GHS/CLP)

Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA – Aflatoxin M1 Standards

Date of creation / revision: 2019-03-08

12. ECOLOGICAL INFORMATION

12.1. Toxicity

UNICITY	
Aquatic Toxicity (Metl	nanol):
Fish toxicity	
LC50	15400 mg/l/96 h
Daphnia toxicity	
EC5	>10000 mg/L/72 h (Entosiphon sulcatum) (Lit)
EC50	>10000 mg/L/48 h (Daphnia magna) (IUCLID)
Algeal toxicity	
IC5	8000 mg/L/8 d (Scenedesmus quadricauda) (IUCLID)
Bacterial toxicity	
EC5	6600 mg/L/16 h (Pseudomonas putida) (IUCLID)

12.2. Persistence and degradability

Easily biodegradable.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

No further relevant information available.

Ecotoxical effects:

Remark: Water hazard class 1 (German Regulation) (Self-assessment) – Do not allow to enter waters, sewers or soil.

12.5. Results of PBT and vPvB assessment

PBT: Not applicable. **vPvB:** Not applicable.

12.6. Other adverse effects

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

Recommendation: This material and its container must be disposed of as hazardous waste. The disposal is regionally differently regulated, therefore the kind of disposal is to be inquired at the responsible authorities.

Uncleaned packaging:

Recommendation: Die Disposal according to official regulations.

Recommended Cleansing agents: Water, if necessary together with cleansing agents.



According to 1272/2008/EC (GHS/CLP)

Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA – Aflatoxin M1 Standards

Date of creation / revision: 2019-03-08

14. TRANSPORT INFORMATION

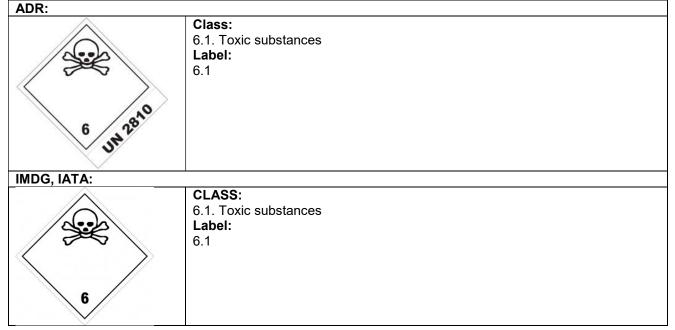
14.1. UN-Number

ADR, IMDG, IATA: UN2810

14.2. UN proper shipping name

ADR: "2810 TOXIC LIQUID, ORGANIC, N.A.G. (METHANOL)" IMDG, IATA: "TOXIC LIQUID, ORGANIC, N.O.S. (METHANOL)

14.3. Transport hazard class(es)



14.4. Packing group ADR, IMDG, IATA: ||

14.5.Environmental hazards Marine pollutant: No.

14.6. Special precautions for user Danger code (Kemler): 60 **EMS-Number:** F-A, S-A

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

Transport/Additional information (ADR)	
Limited quantities (LQ) 1 L	
Transport category	2
Tunnel restriction code	E

UN "Model Regulation": 2810 TOXIC LIQUID, ORGANIC, 6.1, II.



According to 1272/2008/EC (GHS/CLP)

Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA – Aflatoxin M1 Standards

Date of creation / revision: 2019-03-08

15. REGULATORY INFORMATION

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

National regulations:

Information about limitation of use:

Employment restrictions concerning juveniles must be observed. Employment restrictions concerning juveniles must be observed.

Water hazard class:

Water hazard class 1 (Self assessment): slightly hazardous for water.

Technical instructions air:

Class	Share in %
Water	50
1	100

15.2. Chemical safety assessment

A chemical saftety assessment has not been carried out

16. OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases:

Phrase	Definition
H301	Toxic if swallowed
H311	Toxic in contact with skin
H331	Toxic if inhaled
H370	Causes damage to organs
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.

Department issuing MSDS:Department R & DContact:0049-431-71922-0, info@demeditec.de

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA) ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agree-

ment concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)

LD50: Letale Dose, 50 percent (Not relevant for classification)

LC50: Letale concentration, 50 percent (Not relevant for classification)



Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA – Stop Solution

Date of creation / revision: 2019-03-08

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

1.1. Product identifier	
Trade name:	Aflatoxin M1 ELISA
Article Number:	DEAM1E01

Components:

- 0) Microtiter Plate
 1) Substrate Solution
 2) Antibody Solution
 3) Conjugate
 4) Washing Solution (10x Concentrate)
 5) Sample Diluent
- 6) Aflatoxin Standards
- 7) Stop Solution

Concerning safety the microtiter plate (0) is inoffensive and for this reason not part of this document. The mixtures 1 - 5, due to coincident categorization, are combined as a group and treated separately above. The mixtures 6 (standards) are also treated in a separate safety data sheet above. The mixture 7 (Stop Solution) is the object of this safety data sheet and is dealt with below.

1.2. Application of the substance / the preparation Stop Solution as part of the Aflatoxin M1 ELISA.

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier:	Demeditec Diagnostics GmbH Lise-Meitner-Str. 2
	24145 Kiel
	Germany
	Tel.: +49(0)431 / 71922-0
eMail-Address of the qualified person:	info@demeditec.de

1.4. Emergency telephone number

In case of further inquiry please contact the telephone number +49(0)431 / 71922-0 (technical service, business hours 8 a.m. to 4:30 p.m.).

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or Directive 1999/45/EC: X_i, Irritant

R36/38: Irritating to eyes and skin

Classification according to Regulation (EC) No 1272/2008:

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Information concerning particular hazards for human and environment: The mixture has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Classification system: The classification is according to the latest editions of the EU lists, and extended by company and literature data.



Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA – Stop Solution

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2.2. Label elements

Labeling according to Regulation (EC) No 1272/2008: The product is classified and labelled according to the CLP regulation

Hazard pictograms:



GHS05	
Signal word:	Warning.
Hazard statements:	
H315	Causes skin irritation.
H319	Causes serious eye irritation.
Precautionary statem	ents:
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P362	Take off contaminated clothing and wash before reuse.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

All chemicals are potentially dangerous. They should only be handled by specially trained personnel.		
PBT:	Not applicable.	
vPvB:	Not applicable.	

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures **Description:** Aqueous solution.

Dangerous components:

CAS No.:	7664	02.0
	7664-93-9	
Description:	Sulfur	ic acid
EINECS:	231-	639-5
Index number:	016-02	20-00-8
Elemental Formula:	H ₂ SO ₄	
Molar Mass:	98,08	
Concentration in mixture:	0.5 M	
Classification according to Directive 67/548/EEC or Directive 1999/45/EC:		C R35
Classification according to Regulation (EC) No 1272/2008:		Met Corr. 1 Skin Corr. 1A H290, H314

Additional information: For the wording of the listed risk phrases refer to section 16.



Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA – Stop Solution

Date of creation / revision: 2019-03-08

4. FIRST AID MEASURES



4.1. Description of first aid measures

General information: First aider: Pay attention for self-protection!! Remove any clothing soiled by the product.

After Inhalation: Remove to fresh air. I breathing is difficult, give oxygen. Seek medical advice immediately.

After skin contact: Immediately rinse with water. After massive or prolonged skin contact: Seek medical advice.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing: Rinse out mouth and drink a glass of water. Do not induce vomiting. If there is any trouble seek medical help.

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

No further relevant information available.

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

No further relevant information available.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions. CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. **for safety reasons unsuitable extinguishing agents:** For this mixture no limitations of extinguishing agents are given.

5.2. Special hazards arising from the substance or mixture

Ambient fire may liberate hazardous vapours. In the event of fire development of hazardous combustion gases or vapours possible. In case of fire, the following gases can be released: Sulphur dioxide, carbon monoxide and carbon dioxide.

5.3. Important Advice for firefighters

Protective equipment: Wear self-contained respiratory protective device. Wear fully protective suit.



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Trade name: Demeditec Aflatoxin M1 ELISA – Stop Solution

Date of creation / revision: 2019-03-08

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective clothing. Keep away unprotected persons. Avoid eye or skin contact.

6.2. Environmental precautions

Do not allow to enter sewers/ground water or penetrate the soil.

6.3. Methods and material for containment and cleaning up

Absorb with liquid binding material (sand diatomite, acid binders, universal binders, sawdust). Dispose of the material according to regulations. Ensure adequate ventilation.

6.4. Reference to other sections

See section 7 for information on safe handling. See section 8 for information on personal protection requirement. See section 13 for disposal information.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

No special precautions are necessary if used correctly.

Information about fire - and explosion protection: No special measures required.

7.2. Conditions for safe storage, including any incompatibilities Storage:

Requirements to be met by storerooms and receptables: Store at a cool place. Do not store in corrodible metal. Provide acid-resistant floor.

Information about storage in one common storage facility: Store away from foodstuffs. Further information about storage conditions: None. Recommended storage temperature: 2-8°C

7.2. Specific end use(s)

No further relevant information available.



According to 1272/2008/EC (GHS/CLP)

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Trade name: Demeditec Aflatoxin M1 ELISA – Stop Solution

Date of creation / revision: 2019-03-08

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional information about design of technical facilities: No further data; see item 7.

8.1. Control parameters

Ingredients with limit values that require monitoring at workplace:		
7664-93-9 Sulphuric acid		
AGW (Germany):	0.1 E mg/m ³	
	1 (I); DFG, EU, H, Y	
IOELV (EU):	0.05 mg/m ³	

DNEL values (Sulphuric acid):

workers		
long-term exposition – local effects:		
Inhalativ:	DNEL	0.05 mg/m ³ (worker)
short-term exposition – local effects:		
Inhalativ:	DNEL	0.1mg/m ³ (worker)

PNEC values (Sulphuric acid):

	8.8 mg/L (sewage treatment plant)
	0.002 mg/kg (sea water sediment)
PNEC	0.25 mg/L (Meerwasser)
	0.002 mg/kg (Süßwassersediment)
	0.0025 mg/L (fresh water)

Additional information: The lists valid during the making were used as basis.



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8.2. Exposure controls

Personal protective equipment:

General protective and hygienic measures: Wash hands before breaks and at the end of work. Keep away from foodstuffs, beverages and feed. Avoid contact with the eyes and skin. Immediately remove all soiled and contaminated clothing.

Individual protection measures: Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier. **Respiratory protection:**



Required when vapours/areosols are generated.

Protection of hands:



Protective gloves – The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves: Nitrile, thickness: \geq 0.11 mm. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material: Value of the permeation: Level ≥ 6 . The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:



Body protection:



Protective work clothing.



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9. PHYSICAL AND CHEMICAL PROPERTIES

Property	hemical properties Stop Solution (0.5 M Sulphuric acid)	
General information		
Appearance:		
Form:	fluid	
Colour:	colourless	
Odour:	odourless	
Odour threshold:	No information available	
pH-value at 25°C:	~ 0,6	
Change in condition:		
Melting point/ Melting range:	No information available	
Boiling point/Boiling range:	100°C	
Flash point:	No information available	
Flammability (solid, gaseous)	No information available	
Ignition temperature:	No information available	
Decomposition temperature:	No information available	
Self-igniting:	The mixture is not self-igniting	
Danger of explosion:	The mixture does not present an explosion hazard	
Explosion limits:		
Lower:	No information available	
Upper:	No information available	
Oxidizing properties	No information available	
Vapour pressure at 20 °C:	23 hPa	
Density:		
Density at 20 °C:	1,03 g/cm ³	
Vapour density:	No information available	
Evaporation rate:	No information available	
Solubility in / Miscibility with water:	Fully miscible	
Partition coefficient (n-Octanol/Water)	No information available	
Viscosity:		
Dynamic:	No information available	
Kinematic:	No information available	

9.2. Other information

No further relevant information available.



According to 1272/2008/EC (GHS/CLP)

Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA – Stop Solution

Date of creation / revision: 2019-03-08

10. STABILITY AND REACTIVTY

10.1. Reactivity

See section 10.3.

10.2. Chemical stability

Thermal decomposition / conditions to be avoided

No decomposition if used and stored according to specifications.

10.3. Possibility of hazardous reactions

Reacts with alkali (lyes).

10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No dangerous decomposition products known. In case of fire see item 5.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity:

LD/LC50 values relevant for classification: Quantitative data on the toxicity of this product are not available.

Primary irritant effect:

On the skin: Irritant to skin and mucous membranes.

On the eyes: Irritant.

After inhalation: Irritant to skin and mucous membranes.

Sensitization: No sensitizing effects known.

CMR effects:

Germ cell mutagenicity: No information available.

Carcinogenicity: No information available.

Reproductive toxicity: No information available.

Aspiration hazard:

No aspiration toxicity classification.

Specific target organ toxicity - single exposure:

The mixture is not classified as specific target organ toxicant, single exposure.

Specific target organ toxicity – repeated exposure:

The mixture is not classified as specific target organ toxicant, repeated exposure.

Additional toxicological information: We have no description of any toxicological symptoms.

11.2. Further information

The product should be handled with the care usual when dealing with chemicals.



12.

Safety Data Sheet

According to 1907/2006/EC, Article 31 (REACH) According to 1272/2008/EC (GHS/CLP)

Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA – Stop Solution

Date of creation / revision: 2019-03-08

ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity:

Quantitative data on the ecological effect of this product are not available.

12.2. Persistence and degradability

No further relevant information available.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

No further relevant information available.

Ecotoxical effects:

Remark: Water hazard class 1 (German Regulation) (Self-assessment) – Do not allow to enter waters, sewers or soil.

12.5. Results of PBT and vPvB assessment

PBT: Not applicable. **vPvB:** Not applicable.

12.6. Other adverse effects

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Recommendation: This material and its container must be disposed of as hazardous waste. The disposal is regionally differently regulated, therefore the kind of disposal is to be inquired at the responsible authorities.

Uncleaned packaging:

Recommendation: Die Disposal according to official regulations.

Recommended Cleansing agents: Water, if necessary together with cleansing agents.



According to 1272/2008/EC (GHS/CLP)

Version Nr. 2

Trade name: Demeditec Aflatoxin M1 ELISA – Stop Solution

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14. TRANSPORT INFORMATION

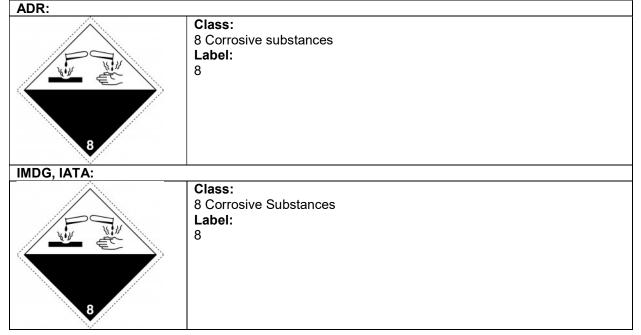
14.1. UN-Number

ADR, IMDG, IATA: UN2796

14.2. UN proper shipping name

ADR: "2796 Battery fluid, acid or Sulphuric acid with not more than 51 percent acid, N.O.S." **IMDG, IATA:** "SULFURIC ACID, N.O.S."

14.3.	Transport	hazard	class	es)
					_



14.4. Packing group ADR, IMDG, IATA: ||

14.5.Environmental hazards Marine pollutant: No.

14.6. Special precautions for user Warning: Corrosive substances. **Danger code (Kemler):** 80 **EMS number:** F-A, S-B

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

Transport/Additional information (ADR)	
Limited quantities (LQ)	5 L
Transport category	3
Tunnel restriction code	E

UN "Model Regulation": 2796 Battery fluid, acid or Sulphuric acid with not more than 51 percent acid, N.O.S., 8, II



Safety Data Sheet

According to 1907/2006/EC, Article 31 (REACH) According to 1272/2008/EC (GHS/CLP)

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15. REGULATORY INFORMATION

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

National regulations:

Information about limitation of use: Employment restrictions concerning juveniles must be observed.

Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out.

16. OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases:

Phrase	Definition
H315	Causes skin irritation.
H319	Causes serious eye irritation.
R36/38	Irritating to eyes and skin.

Department issuing MSDS:	Department R & D
Contact:	0049-431-71922-0, info@demeditec.de

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA) ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agree-

ment concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)

LD50: Letale Dose, 50 percent (Not relevant for classification)

LC50: Letale concentration, 50 percent (Not relevant for classification)