



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416

Date of creation / revision: 2019-03-08

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name: Enzyme immunoassays (various) for the determination of human antibodies against food antigens.

Article Number: DE40416

Components:

- 0) Mikrotiter Plate
- 1) Reference Strips (if available)
- 2) Enzyme Conjugate
- 3) Washing Buffer (10x Concentrate)
- 4) Sample Diluent
- 5) Standards/Controls (if available)
- 6) Substrate
- 7) Stop Solution

Concerning safety The Microtiter Plate (0) as well as the Reference Strips (1) are inoffensive and for this reason not part of this document. The mixtures 2 – 6, due to coincident categorization, are combined As a group and treated and dealt with below. The mixtures 6 (Substrate) and 7 (Stop Solution) are addressed in a separate safety data sheets below.

1.2. Application of the substance / the preparation

Enzyme immunoassay based on microtiter plate for the detection and quantitative determination of human antibodies against food antigens in serum or plasma; in-vitro diagnostic.

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 719220

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:

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: Void.

Hazard pictograms: Void.

Signal word: 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.

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: Dioxid, carbon monoxide and carbon dioxide.

5.3. Important Advice for firefighters

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



Safety Data Sheet

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

Version Nr. 2

Trade name: *IgG Screen Nutritional 16 ELISA DE40416*

Date of creation / revision: 2019-03-08

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 receptacles: 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.

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:

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:



Not required.

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.

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.

Eye protection:



Tightly sealed goggles.

Body protection:



Protective work clothing.



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416

Date of creation / revision: 2019-03-08

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Property	Enzyme Conjugate	Washing Buffer (10x Conc.)	Sample Diluent	Standards/ Controls (if available)
General information				
Appearance:				
Form:	fluid	fluid	fluid	fluid
Colour:	green/yellow	colourless	red	red
Odour:	odourless	odourless	odourless	odourless
Odour threshold:	No information available	No information available	No information available	No information available
pH-value at 25°C:	5.5 – 6.5	6.2 – 7.2	5.6 – 6.6	5.6 – 6.6
Change in condition:				
Melting point/ Melting range:	No information available	No information available	No information available	No information available
Boiling point/Boiling range	100 °C	100 °C	100 °C	100 °C
Flash point:	No information available	No information available	No information available	No information available
Flammability (solid, gaseous)	No information available	No information available	No information available	No information available
Ignition temperature:				
Decomposition temperature:	No information available	No information available	No information available	No information available
Self-igniting:	The mixture is not self-igniting			
Danger of explosion:	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard
Explosion limits:				
Lower:	No information available	No information available	No information available	No information available
Upper:	No information available	No information available	No information available	No information available
Oxidizing properties	No information available	No information available	No information available	No information available
Vapour pressure at 20 °C:	No information available	No information available	No information available	No information available
Density:				
Density at 20 °C:	No information available	No information available	No information available	No information available
Vapour density:	No information available	No information available	No information available	No information available
Evaporation rate:	No information available	No information available	No information available	No information available
Solubility in / Miscibility with water:	Fully miscible	Fully miscible	Fully miscible	Fully miscible
Partition coefficient (n-Octanol/Water)	No information available	No information available	No information available	No information available
Viscosity:				
Dynamic:	No information available	No information available	No information available	No information available
Kinematic:	No information available	No information available	No information available	No information available

9.2. Other information

No further relevant information available.



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416

Date of creation / revision: 2019-03-08

10. Stability and reactivity

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

Light, heat, humidity

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 the mixtures are not available.

Primary irritant 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.

Specific target organ toxicity – single exposure: 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.



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416

Date of creation / revision: 2019-03-08

12. 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.

Ecotoxicological 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.

14. 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.



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416

Date of creation / revision: 2019-03-08

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

National regulations:

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.

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 (0) 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)



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416 - Substrate

Date of creation / revision: 2019-03-08

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name:

Enzyme immunoassays (various) for the determination of human antibodies against food antigens – Substrate.

Article Number: DE40416 - Substrate

Components:

- 0) Mikrotiter Plate
- 1) Reference Strips (if available)
- 2) Enzyme Conjugate
- 3) Washing Buffer (10x Concentrate)
- 4) Sample Diluent
- 5) Standards/Controls (if available)
- 6) Substrate
- 7) Stop Solution

Concerning safety The Microtiter Plate (0) as well as the Reference Strips (1) are inoffensive and for this reason not part of this document. The mixtures 2 – 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 below. The mixture 6 (Substrate) is the object of this safety data sheet and is dealt with below.

1.2. Application of the substance / the preparation

Substrate as part of Enzyme immunoassays based on microtiter plate for the detection and quantitative determination of human antibodies against food antigens in serum or plasma; in-vitro diagnostic.

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 719220

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 Regulation (EC) No 1272/2008:

The mixture is 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 mixture is 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: Void.

Hazard pictograms: Void.

Signal word: Void.

Hazard statements: Void.

Trade name: *IgG Screen Nutritional 16 ELISA DE40416 - Substrate*

Date of creation / revision: 2019-03-08

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.:	111-42-2	75-05-8
Description:	Diethanolamine	Acetonitrile
EINECS:	203-868-0	200-835-2
Index number:	603-071-00-1	608-001-00-3
Elemental Formula:	$\text{NH}(\text{CH}_2\text{CH}_2\text{OH})_2$	CH_3CN
Molar Mass:	105.14	41.05
Concentration in mixture:	< 8%	< 3%
Classification according to Regulation (EC) No 1272/2008:	   H302, H315 H318, H373	  H225, H302 H312, H319 H332

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: Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

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. Immediately seek medical advice.

After swallowing: Rinse out mouth and drink a glass of water. Do not induce vomiting. Immediately seek medical advice.



Safety Data Sheet

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

Version Nr. 2

Trade name: *IgG Screen Nutritional 16 ELISA DE40416 - Substrate*

Date of creation / revision: 2019-03-08

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.

Product non-combustible.

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

In the event of fire development of hazardous combustion gases or vapours possible.

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

Do not inhale vapours. 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

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

Handle and open container with care. Keep containers, equipment and working place clean.

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 receptacles: 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

7.3. Specific end use(s)

No further relevant information available.

Trade name: *IgG Screen Nutritional 16 ELISA DE40416 - Substrate*

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:

111-42-2 Diethanolamine	
MAK (TRGS 900)	not listed
BGW (TRGS 903)	not listed
75-05-7 Acetonitrile	
MAK (TRGS 900)	34 mg/m ³
BGW (TRGS 903)	not listed

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:



Not required.

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: ≥ 0.2 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.

Safety Data Sheet

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

Version Nr. 2

Trade name: *IgG Screen Nutritional 16 ELISA DE40416 - Substrate*

Date of creation / revision: 2019-03-08

Eye protection:



Tightly sealed goggles.

Body protection:



Protective work clothing.



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416 - Substrate

Date of creation / revision: 2019-03-08

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Property	Substrate
General information	
Appearance:	
Form:	fluid
Colour:	colourless
Odour:	odourless
Odour threshold:	No information available
pH-value at 25°C:	9.4 – 9.6
Change in condition:	
Melting point/ Melting range:	No information available
Boiling point/Boiling range:	102°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:	No information available
Density:	
Density at 20 °C:	1.02 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.



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416 - Substrate

Date of creation / revision: 2019-03-08

10. Stability and reactivity

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

No hazardous reactions known.

10.4. Conditions to avoid

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the product).

10.5. Incompatible materials

Heavy metal salts, complex forming agents and phosphatases (will not cause a dangerous reaction, but destroys the quality of the product).

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:

111-42-2 Diethanolamine

Rat	LD50 (oral)	676 mg/kg
-----	-------------	-----------

75-05-7 Acetonitrile

Rat	LD50 (oral)	1372 mg/kg
-----	-------------	------------

Mouse	LD50 (oral)	617 mg/kg
-------	-------------	-----------

Primary irritant effect:

On the skin:

111-42-2 Diethanolamine

Rabbit	LD50 (dermal)	8328 mg/kg
--------	---------------	------------

Causes skin irritation.

On the eyes: Serious eye damage/irritation.

After inhalation: May cause respiratory irritation.

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: May damage organs after long lasting or repeated exposure..

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



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416 - Substrate

Date of creation / revision: 2019-03-08

11.2. Further 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.

12. Ecological information

12.1. Toxicity

Aquatic toxicity:

111-42-2 Diethanolamine		
Mosquitofish (<i>Gambusia affinis</i>)	LC50 (mg/L/96h)	1400
Ide (<i>Leuciscus idus</i>)	LC50 (mg/L/96h)	1430
Water Flea (<i>Daphnia magna</i>)	EC50 (mg/L/48h)	110
Algae (<i>Desodermus subsicatus</i>)	IC50 (mg/L/72h)	75
<i>Pseudomonas putida</i>	EC50 (mg/L/16h)	>1000
75-05-7 Acetonitrile		
Fathead minnow (<i>Pimephales promelas</i>)	LC50 (mg/L/96h)	1640
Japanes rice fish (<i>Oryzias latipes</i>)	LC50 (mg/L/96h)	>100
Water Flea (<i>Daphnia magna</i>)	EC50 (mg/L/48h)	>1000
Green algae (<i>Pseudokirchneriella subsicatata</i>)	IC50 (mg/L/72h)	>1000
<i>Pseudomonas putida</i>	EC50 (mg/L/16h)	680

12.2. Persistence and degradability

Biological degradability:

111-42-2 Diethanolamine	94%/30d, easily biologically degradable
75-05-7 Acetonitrile	70%/21d, easily biologically degradable

12.3. Bioaccumulative potential

Distribution:

111-42-2 Diethanolamine	$\log P(o/w) = -2.18$
75-05-7 Acetonitrile	$\log P(o/w) = -0.34$

.There is no Bioaccumulation expected ($\log P(o/w) < 1$)

12.4. Mobility in soil

No further relevant information available.

Ecotoxicological 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

Henry-constant for acetonitril at 20°C: 3.5 Pa*m³/mol; no transition from aqueous solution to air expected.



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416 - Substrate

Date of creation / revision: 2019-03-08

13. Disposal considerations

1

3.1. 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.

14. 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

National regulations:

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.

16.



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416 - Substrate

Date of creation / revision: 2019-03-08

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
H225	Highly flammable liquid and vapour
H302	Harmful if swallowed
H312	Harmful in contact with skin
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H373	May cause damage to organs through prolonged or repeated exposure

Department issuing MSDS: Department R & D

Contact: 0049(0) 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)



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416 – 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:

Enzyme immunoassays (various) for the determination of human antibodies against food antigens – Stop Solution.

Article Number:

various

Components:

- 0) Mikrotiter Plate
- 1) Reference Strips (if available)
- 2) Enzyme Conjugate
- 3) Washing Buffer (10x Concentrate)
- 4) Sample Diluent
- 5) Standards/Controls (if available)
- 6) Substrate
- 7) Stop Solution

Concerning safety The Microtiter Plate (0) as well as the Reference Strips (1) are inoffensive and for this reason not part of this document. The mixtures 2 – 5, due to coincident categorization, are combined As a group and treated separately above . The mixture 6 (Substrate) is 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 Enzyme immunoassays based on microtiter plate for the detection and quantitative determination of human antibodies against food antigens in serum or plasma; in-vitro diagnostic.

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 719220

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:

C, Corrosive

R35: Causes severe burns.

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

Met. Corr. 1 H290 May be corrosive to metals.

Skin Corr. 1A H314 Causes severe skin burns and eye damage.

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.

Trade name: *IgG Screen Nutritional 16 ELISA DE40416 – Stop Solution*

Date of creation / revision: 2019-03-08

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:

Danger

Hazard statements:

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

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately 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:

Aqueous solution.

Dangerous components:

CAS No.:	1310-73-2	
Description:	Sodium hydroxide	
EINECS:	215-185-5	
Index number:	011-002-00-6	
Elemental Formula:	NaOH	
Molar Mass:	39.997	
Concentration in mixture:	1 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.

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: Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

After skin contact: Immediately rinse with water. Swab with polyethylen glycol 400. After massive or prolonged skin contact: Seek medical advice.

After eye contact: Rinse opened eye for several minutes under running water. Immediately seek medical advice.

After swallowing: Rinse out mouth and drink a glass of water. Do not induce vomiting. Risk of perforation! Immediately seek medical advice.

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.

Product non-combustible.

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

In the event of fire development of hazardous combustion gases or vapours possible.

5.3. Important Advice for firefighters

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



Safety Data Sheet

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

Version Nr. 2

Trade name: *IgG Screen Nutritional 16 ELISA DE40416 – Stop Solution*

Date of creation / revision: 2019-03-08

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not inhale vapours. 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 (e.g. Basosorb).

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

Handle and open container with care.

Keep containers, equipment and working place clean.

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 receptacles: Do not use aluminium, tin or zinc containers.

Do not store in corrodible metal.

Information about storage in one common storage facility: Store away from foodstuffs.

Further information about storage conditions: None.

Recommended storage temperature: 2-8°C

7.3. Specific end use(s)

No further relevant information available.

Trade name: *IgG Screen Nutritional 16 ELISA DE40416 – 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:

1310-73-2 Sodium Hydroxide

WEL (Great Britain):

2 mg/m³

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:



Required when vapours/aerosols are generated. Filter P2 (colour code: white).

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: ≥ 0.2 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.

Trade name: *IgG Screen Nutritional 16 ELISA DE40416 – Stop Solution*

Date of creation / revision: 2019-03-08

Eye protection:



Tightly sealed goggles.

Body protection:



Protective work clothing.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Property	Stop Solution (1 M Sodium Hydroxide)
General information	
Appearance:	
Form:	fluid
Colour:	colourless
Odour:	odourless
Odour threshold:	No information available
pH-value at 25°C:	~14
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:	1,22 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.



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416 – Stop Solution

Date of creation / revision: 2019-03-08

10. Stability and reactivity

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

Strong reactions with compounds mentioned below.

10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

Ammonium compounds, light metals, cyanides, organic flammable substances, acids, metals, oxidisables substances, acetone, phenol, organic nitro compounds, powdered alkaline earth metal.

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: Strong caustic effect on skin and mucous membranes.

On the eyes: Burns, risk of blindness.

After inhalation: Irritant to mucous membranes, coughing, breathlessness.

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

After swallowing: burns in the mouth, throat, oesophagus and gastrointestinal tract, risk of perforation.



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416 – Stop Solution

Date of creation / revision: 2019-03-08

12. 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.

Ecotoxicological 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.

Trade name: *IgG Screen Nutritional 16 ELISA DE40416 – Stop Solution*

Date of creation / revision: 2019-03-08

14. Transport information

14.1. UN-Number

ADR, IMDG, IATA: UN1824

14.2. UN proper shipping name

ADR: "1824 SODIUM HYDROXIDE SOLUTION"

IMDG, IATA: „ SODIUM HYDROXIDE SOLUTION"

14.3. Transport hazard class(es)

ADR:

	<p>Class: 8 Corrosive substances</p> <p>Label: 8</p>
--	--

IMDG, IATA:

	<p>Class: 8 Corrosive Substances</p> <p>Label: 8</p>
--	--

14.4. Packing group

ADR, IMDG, IATA: II

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“:

UN1824, SODIUM HYDROXIDE SOLUTION, 8, II



Safety Data Sheet

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

Version Nr. 2

Trade name: IgG Screen Nutritional 16 ELISA DE40416 – Stop Solution

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.

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.

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
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
R35	Causes severe burns.

Department issuing MSDS: Department R & D

Contact: 0049(0) 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)