

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

Product identifier

Substance name: ADMA Fast ELISA Article number.: R E F EA212/96

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

Relevant identified uses:

Reagent / Immunoassay

For in-vitro diagnostic use only. For professional use only.

Uses advised against:

/

Details of the supplier of the safety data sheet:

Supplier

DLD Diagnostika GmbH

Address

Adlerhorst 15
22459 Hamburg
Germany

Information contact

E-Mail: contact@dld-diagnostika.de

Internet: www.dld-diagnostika.de

Telephone / Fax / E-Mail

Tel +49 (0) 40 555 87 10 / Fax +49 (0) 40 555 87 111 / contact@dld-diagnostika.de

1.4 Emergency Telephone Number

Tel +49 (0) 40 555 87 10

2. Hazards identification

Classification of the substance or mixture

Some components of this kit are containing hazardous reagents. These components are marked with the adequate hazard label:

Solvent

Acylation Buffer

Enzyme Conjugate

Corresponding safety data sheets: see following safety data sheets (below)

Following components (see 3. Composition/information on ingredients) contain no hazardous reagents in concentrations to be declared.

3. Composition/information on ingredients

Microtiterstrips	Polystyrol-Microtiterplate coated with specific antigen
Standards	Diluted antigen
Controls	Diluted antigen
Equalizing Reagent	Protein, lyophilized
Acylation Reagent	Acylation reagent, lyophilized
Antiserum	Diluted specific antiserum (rabbit), neutral buffer solution, stabilized
Reaction Plate	Polypropylene-Microtiterplate
Wash Buffer	Diluted buffer solution with detergent, neutral, concentrate
Substrate	Slightly bluish, acidic liquid
Stop Solution	0.3 mol/l sulphuric acid
Foil	/

Components above contain no hazardous reagents in concentrations to be declared.

4. First aid measures

General informations:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

After inhalation

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. If unconsciousness, bedding and transport in recovery position.

After skin contact

Generally the product does not irritate the skin.

After eye contact

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

After swallowing

If symptoms persist consult doctor.

5. Firefighting measures

Extinguishing media

Suitable:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

Environmental precautions

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up

Absorb with liquid-binding material.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7. Handling and storage

Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Always close receptacle after use.

Prevent formation of aerosols.

Information about fire - and explosion protection:

Keep respiratory protective device available.

Aerosol and dust generation preventions

Open and handle receptacle with care.

Always close receptacle after use.

Environmental precautions

Do not allow to enter sewers/ surface or ground water.

General hygiene measures

- Eating, drinking or smoking is prohibited in working areas.

- Wash hands after handling.

- Remove contaminated clothing and protective equipment before entering any food handling areas.

Conditions for safe storage, including any incompatibilities

No special requirements

8. Exposure controls/personal protection

Occupational exposure limit sulphuric acid:

Inhalable fraction: 0,1 mg/m³

Personal protective equipment

Eye / Face protection

Tightly sealed goggles.

Skin protection

Protective Gloves

Material of gloves

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 can not be calculated in advance and has therefore to be checked prior to the application. The quality of the protective gloves must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

The exact break through time: Call the manufacturer of the protective gloves and this has to be observed.

Other skin protection measures

Lab coat.

Respiratory protection

No special requirements.

Thermal hazards

No special requirements.

Environmental exposure controls

See sections 6 und 7.

9. Physical and chemical properties

Microtiterstrips	Polystyrol-Microtiterplate in foil packet.
Standards	Colorless liquid.
Control	Colorless liquid.
Equalizing Reagent	Powder
Acylation Reagent	Powder
Antiserum	Colored, neutral liquid
Reaction Plate	Polypropylene-Microtiterplate in foil packet.
Wash Buffer	Colorless, neutral liquid
Stop Solution	Colorless, acidic liquid, pH < 1.
Foil	Adhesive foil in foil packet.

10. Stability and reactivity

Stability of components: See Label.

Used according to intended use and stored under appropriate conditions no dangerous reactions known.

Conditions to avoid

Substrate is light-sensitive.

11. Toxicological information

Used according to intended use no toxicological reactions known.

12. Ecological information

Used according to intended use no ecological reactions known.

13. Disposal considerations

Dispose of waste according to applicable local, state, and federal regulations.

14. Transport information

This product is not subject to official transport regulations

15. Regulatory information

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

National Regulations

Water hazard class

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

Further relevant regulations

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Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

16. Other information

Indication of changes

Entire Revision

Key literature references and sources for data

Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

Further Informationen

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. This shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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

1.1 Product identifier

Substance name: Solvent

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

Relevant identified uses:

Reagent / Immunoassay

For in-vitro diagnostic use only. For professional use only.

Uses advised against:

/

1.3 Details of the supplier of the safety data sheet:

Supplier

DLD Diagnostika GmbH

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1.4 Emergency Telephone Number

Tel +49 (0) 40 555 87 10

2. Hazards identification

2.1 Classification of the substance or mixture

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

Flam. Liq. 3 H226

2.2 Label elements

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

Hazard pictograms / Signal word:



Warning / GHS02

Hazard-determining components of labelling

/

Hazard statements:

H226: Flammable liquid and vapour.

Precautionary statements

P210	Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
P233	Keep container tightly closed.
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.
P264	Wash hands thoroughly after handling.
P305+P351+P338	IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313	If eye irritation persists Get medical advice/attention.
P501	Dispose of contents/container to applicable local, state, and federal regulations.

Supplemental Hazard information (EU)

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2.3 Other hazards

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3. Composition/information on ingredients

3.1 Substances

This product is a mixture.

3.2 Mixture

Substance: DMSO

EG-Nr.: 200-664-3 CAS-Nr. : 67-68-5

Content: 50 - 100%

Classification according to (EG) Nr. 1272/2008:

No hazardous product.

4. First aid measures

4.1 Description of first aid measures

General informations:

Immediately remove any clothing soiled by the product.

After inhalation

Supply fresh air; consult 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. Then consult a doctor.

After swallowing

Rinse out mouth. Do not induce vomiting; call for medical help immediately.

Risk of aspiration! Keep airways free.

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:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

Combustible. Vapours are heavier than air and may spread along floors.

Forms explosive mixtures with air at ambient temperatures. Beware of backfiring.

5.3 Advice for fire-fighters

Protective equipment:

Wear self-contained respiratory protective device. In order to avoid contact with skin, keep a safety distance and wear suitable protective clothing. Wear fully protective suit.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.
Do not inhale steams/aerosols. Keep away from ignition sources.
Avoid substance contact. Ensure adequate ventilation

6.2 Environmental precautions

Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material.
Dispose contaminated material as waste according to item 13.
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 equipment.
See Section 13 for disposal information.

7. Handling and storage

7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. Open and handle receptacle with care.
Always close receptacle after use. Prevent formation of aerosols.

Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Aerosol and dust generation preventions

Open and handle receptacle with care.
Always close receptacle after use.

Environmental precautions

Do not allow to enter sewers/ surface or ground water.

General hygiene measures

- Eating, drinking or smoking is prohibited in working areas.
- Wash hands after handling.
- Remove contaminated clothing and protective equipment before entering any food handling areas.

7.2 Conditions for safe storage, including any incompatibilities

Information about storage conditions

No special requirements.

Requirements for storage rooms and vessels

No special requirements.
Keep receptacle tightly sealed.

Storage class: /

7.3 Specific end uses

No further relevant information available.

8. Exposure controls/personal protection

8.1 Control parameters

8.1.1 Components with workplace control parameters

Limit Value Type (AGW) Germany

Substance:	DMSO, CAS-Nr.: 67-68-5
Source :	AGW
Value :	160 mg/m ³ , TGRS, exposure limit in air at workplace

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Ensuring good ventilation.
This can be achieved by local suction or general exhaust air.

8.2.2 Personal protective equipment

General protective and hygienic measures

Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

Eye / Face protection

Tightly sealed goggles.

Skin protection

Protective Gloves

Material of gloves

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 can not be calculated in advance and has therefore to be checked prior to the application. The quality of the protective gloves must be chosen as a function of the specific working place concentration and quantity of hazardous substances.
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
The exact break through time: Call the manufacturer of the protective gloves and this has to be observed.

Other skin protection measures

Lab coat.

Respiratory protection

Respiratory protection: If limit value of working place is exceeded.

Thermal hazards

No special requirements.

8.2.3 Environmental exposure controls

See sections 6 und 7.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	
- Form:	Liquid
- Colour:	Yellow
Odour:	No data available
Odour Threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper/lower flammability or explosive limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Relative density:	No data available
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available

9.2 Other safety information

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10. Stability and reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

Reacts with reducing agents.
Reacts with strong acids and oxidizing agents.
Forms explosive gas mixture with air.

10.4 Conditions to avoid

Heat, flames and sparks.

10.5 Incompatible materials

Incompatible with various plastics and metals..

10.6 Hazardous decomposition products

No dangerous decomposition products known.

11. Toxicological information

11.1 Information on toxicological effects

Substance

This product is a mixture.

Mixture

No data available for this mixture.

Acute toxicity

DMSO CAS-Nr.: 67-68-5:

LD50 Oral – rat – 14,500 mg/kg

LD50 Dermal – rat – 40,000 mg/kg

Irritation

Skin: No data available.

Eye: No data available.

Inhalation: No data available.

Corrosivity

No data available.

Sensitisation

No data available.

Repeated dose toxicity

No data available.

Carcinogenicity

No data available.

Mutagenicity

No data available.

Toxicity for reproduction

No data available.

Specific target organ toxicity - single exposure

No data available.

Specific target organ toxicity - repeated exposure

No data available.

12. Ecological information

12.1 Toxicity

No further relevant information 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.

12.5 Results of PBT and vPvB assessment

No further relevant information available.

12.6 Other adverse effects

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

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13. Disposal considerations

13.1 Waste treatment methods

Dispose of waste according to applicable local, state, and federal regulations.

Contaminated packaging

Dispose of packaging according to applicable local, state, and federal regulations.

Waste codes

Confirm precise waste code with the disposer.

Special precautions

No further relevant information available.

14. Transport information

14.1 UN number

/

14.2 UN proper shipping name

ADR/RID

No dangerous good in sense of this transport regulation.

IMDG-Code / ICAO-TI / IATA-DGR

No dangerous good in sense of this transport regulation.

14.3 Transport hazard class(es)

No dangerous good in sense of this transport regulation.

14.4 Packaging group

Material with low danger.

14.5 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: ☐ yes / ☒ no

Marine Pollutant: ☐ yes / ☒ no

14.6 Special precautions for user

See sections 6 -8.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

15. Regulatory information

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

National Regulations

Water hazard class

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

Further relevant regulations

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15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

16. Other information

Indication of changes

Entire Revision

Abbreviations and acronyms

PBT: persistent, bioaccumulative, toxic substance (REACH)

vPvB: very persistent, very bioaccumulative substance (REACH)

REACH: Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

CLP: Regulation on classification, labelling and packaging of substances and mixtures

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International

Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the

International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Key literature references and sources for data

Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

Further Informationen

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. This shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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

1.1 Product identifier

Substance name: Acylation Buffer

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

Relevant identified uses:

Reagent / Immunoassay

For in-vitro diagnostic use only. For professional use only.

Uses advised against:

/

1.3 Details of the supplier of the safety data sheet:

Supplier

DLD Diagnostika GmbH

Address

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1.4 Emergency Telephone Number

Tel +49 (0) 40 555 87 10

2. Hazards identification

2.1 Classification of the substance or mixture

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

Eye Irrit. 2; H319 Skin Irrit. 2; H315

2.2 Label elements

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

Hazard pictograms / Signal words:



Warning GHS07

Hazard-determining components of labelling

/

Hazard statements:

H319 Causes serious eye irritation.

H315 Causes skin irritation

Precautionary statements

P264 Wash hands thoroughly after handling.

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.

P302 + P352 IF ON SKIN: wash with plenty of soap and water.

P332 + P313 IF SKIN irritation occurs: Get medical advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash before reuse.

Supplemental Hazard information (EU):

/

2.3 Other hazards

/

3. Composition/information on ingredients

3.1 Substances

This product is a mixture.

3.2 Mixture

Substance: /

Content : 20 - 40%

Classification according to (EG) Nr. 1272/2008:

Eye Irrit. 2; H319 Skin Irrit. 2; H315

4. First aid measures

4.1 Description of first aid measures

General informations:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

After inhalation

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. If unconsciousness, bedding and transport in recovery position.

After skin contact

Immediately rinse with water.

After eye contact

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

After swallowing

Drink copious amounts of water and provide fresh air. Call for doctor immediately.

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:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Nitrogen oxides (NO_x), Carbon monoxide and carbon dioxide.

5.3 Advice for fire-fighters

Protective equipment: Mount respiratory protective device.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

6.2 Environmental precautions

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material.

Dispose contaminated material as waste according to item 13.

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 equipment.

See Section 13 for disposal information.

7. Handling and storage

7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Always close receptacle after use.

Prevent formation of aerosols.

Information about fire - and explosion protection:

Keep respiratory protective device available.

Aerosol and dust generation preventions

Open and handle receptacle with care.

Always close receptacle after use.

Environmental precautions

Do not allow to enter sewers/ surface or ground water.

General hygiene measures

- Eating, drinking or smoking is prohibited in working areas.

- Wash hands after handling.

- Remove contaminated clothing and protective equipment before entering any food handling areas.

7.2 Conditions for safe storage, including any incompatibilities

Information about storage conditions

No special requirements.

Requirements for storage rooms and vessels

No special requirements.

Keep receptacle tightly sealed.

Storage class: /

7.3 Specific end uses

No further relevant information available.

8. Exposure controls/personal protection

8.1 Control parameters

8.1.1 Components with workplace control parameters

Limit Value Type (AGW) Germany

Not required.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Ensuring good ventilation.

This can be achieved by local suction or general exhaust air.

8.2.2 Personal protective equipment

Eye / Face protection

Tightly sealed goggles.

Skin protection

Protective Gloves

Material of gloves

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 can not be calculated in advance and has therefore to be checked prior to the application. The quality of the protective gloves must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

The exact break through time: Call the manufacturer of the protective gloves and this has to be observed.

Other skin protection measures

Lab coat.

Respiratory protection

Not required.

Thermal hazards

No special requirements.

8.2.3 Environmental exposure controls

See sections 6 und 7.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	
- Form:	Liquid
- Colour:	Blue
Odour:	Odourless
Odour Threshold:	No data available
pH:	8.8 – 9.4
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper/lower flammability or explosive limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Relative density:	No data available
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available

9.2 Other safety information

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10. Stability and reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Avoid contact with: strong oxidizers, strong acids, strong alkali.

10.6 Hazardous decomposition products

Nitrogen oxides (NO_x), Carbon monoxide and carbon dioxide

11. Toxicological information

11.1 Information on toxicological effects

Substance

This product is a mixture.

Mixture

No data available for this mixture.

Acute toxicity

No data available.

Irritation

Skin: Irritant to skin and mucous membranes.

Eye: Irritating effect.

Corrosivity

No corrosive effect known.

Sensitisation

No sensitizing effects known.

Repeated dose toxicity

No data available.

Carcinogenicity

IARC: No component of this product present at a level greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Mutagenicity

No data available.

Toxicity for reproduction

No data available.

Specific target organ toxicity - single exposure

No data available.

Specific target organ toxicity - repeated exposure

No data available.

12. Ecological information

12.1 Toxicity

No further relevant information available.

12.2 Persistence and degradability

The product is easily biodegradable

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

12.5 Results of PBT and vPvB assessment

No further relevant information available.

12.6 Other adverse effects

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13. Disposal considerations

13.1 Waste treatment methods

Dispose of waste according to applicable local, state, and federal regulations.

Contaminated packaging

Dispose of packaging according to applicable local, state, and federal regulations.

Waste codes

Confirm precise waste code with the disposer.

Special precautions

No further relevant information available.

14. Transport information

14.1 UN number

/

14.2 UN proper shipping name

ADR/RID

No dangerous good in sense of this transport regulation.

IMDG-Code / ICAO-TI / IATA-DGR

No dangerous good in sense of this transport regulation.

14.3 Transport hazard class(es)

No dangerous good in sense of this transport regulation.

14.4 Packaging group

Material with low danger.

14.5 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: ☐ yes / ☒ no

Marine Pollutant: ☐ yes / ☒ no

14.6 Special precautions for user

See sections 6 -8.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

15. Regulatory information

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

National Regulations

Water hazard class

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

Further relevant regulations

/

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

16. Other information

Indication of changes

Entire Revision

Abbreviations and acronyms

PBT: persistent, bioaccumulative, toxic substance (REACH)

vPvB: very persistent, very bioaccumulative substance (REACH)

REACH: Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

CLP: Regulation on classification, labelling and packaging of substances and mixtures

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International

Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the

International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Key literature references and sources for data

Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

Further Informationen

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. This shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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

1.1 Product identifier

Substance name: Enzyme Conjugate

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

Relevant identified uses:

Reagent / Immunoassay

For in-vitro diagnostic use only. For professional use only.

Uses advised against:

/

1.3 Details of the supplier of the safety data sheet:

Supplier

DLD Diagnostika GmbH

Address

Adlerhorst 15
22459 Hamburg
Germany

Information contact

E-Mail: contact@dld-diagnostika.de

Internet: www.dld-diagnostika.de

Telephone / Fax / E-Mail

Tel +49 (0) 40 555 87 10 / Fax +49 (0) 40 555 87 111 / contact@dld-diagnostika.de

1.4 Emergency Telephone Number

Tel +49 (0) 40 555 87 10

2. Hazards identification

2.1 Classification of the substance or mixture

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

Skin sensitisation, Category 1, H317

2.2 Label elements

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

Hazard pictograms / Signal words:



Warning GHS07

Hazard-determining components of labelling

Substance: CMIT/MIT: Contains Isothiazole; CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5

Hazard statements:

H317 May causes an allergic skin reaction..

Precautionary statements

P261 Avoid breathing mist, vapors..

P264 Wash hands thoroughly after handling.

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

P302 + P352 IF ON SKIN: wash with plenty of soap and water.

P333 + P313 IF SKIN irritation or rash occurs: Get medical advice/attention.

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 + P364 Take off contaminated clothing and wash before reuse.

Supplemental Hazard information (EU):

EUH208 Contains CMIT/MIT. May produce an allergic reaction.

2.3 Other hazards

/

3. Composition/information on ingredients

3.1 Substances

This product is a mixture.

3.2 Mixture

Substance: CMIT/MIT: Contains Isothiazole; CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5

Content : < 0.0028%

Classification according to (EG) Nr. 1272/2008:

Inhalation: Acute toxicity 3, H331: Toxic if inhaled

Oral: Acute toxicity 3, H301: Toxic if swallowed

Dermal: Acute toxicity 3, H311: Toxic in contact with skin

Aquatic Acute 1, H400: Very toxic to aquatic life

Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects

Skin corrosion 1B, H314: Causes severe skin burns and eye damage

Skin sensitisation 1B, H317: May cause an allergic skin reaction

4. First aid measures

4.1 Description of first aid measures

General informations:

Get medical attention/advice and show safety data sheet. Remove contaminated clothing.

After inhalation

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. If unconsciousness, bedding and transport in recovery position.

After skin contact

Immediately rinse with water.

After eye contact

Rinse opened eye for at least 15 minutes under running water. If possible, remove contact lenses. If symptoms persist, consult a doctor.

After swallowing

Rinse mouth with water thoroughly. Do not induce vomiting without medical advice.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

May cause irritation.

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:

CO₂, powder, foam or water spray.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Nitrogen oxides (NO_x), Carbon monoxide and carbon dioxide.

5.3 Advice for fire-fighters

Protective equipment: Mount respiratory protective device.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

6.2 Environmental precautions

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material.

Dispose contaminated material as waste according to item 13.

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 equipment.

See Section 13 for disposal information.

7. Handling and storage

7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Always close receptacle after use.

Prevent formation of aerosols.

Information about fire - and explosion protection:

Keep respiratory protective device available.

Aerosol and dust generation preventions

Open and handle receptacle with care.

Always close receptacle after use.

Environmental precautions

Do not allow to enter sewers/ surface or ground water.

General hygiene measures

- Eating, drinking or smoking is prohibited in working areas.

- Wash hands after handling.

- Remove contaminated clothing and protective equipment before entering any food handling areas.

7.2 Conditions for safe storage, including any incompatibilities

Information about storage conditions

No special requirements.

Requirements for storage rooms and vessels

No special requirements.

Keep receptacle tightly sealed.

Storage class: /

7.3 Specific end uses

No further relevant information available.

8. Exposure controls/personal protection

8.1 Control parameters

8.1.1 Components with workplace control parameters

Limit Value Type (AGW) Germany

Substance: CMIT/MIT: Contains Isothiazole; CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5

Occupational exposure limit: 0.2 mg/m³ inhalable fraction

Exposure peak limit: 0.4 mg/m³ inhalable fraction

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Ensuring good ventilation.

This can be achieved by local suction or general exhaust air.

8.2.2 Personal protective equipment

Eye / Face protection

Tightly sealed goggles.

Skin protection

Protective Gloves

Material of gloves

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 can not be calculated in advance and has therefore to be checked prior to the application. The quality of the protective gloves must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

The exact break through time: Call the manufacturer of the protective gloves and this has to be observed.

Other skin protection measures

Lab coat.

Respiratory protection

Not required.

Thermal hazards

No special requirements.

8.2.3 Environmental exposure controls

See sections 6 und 7.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	
- Form:	Liquid
- Colour:	Yellow-brown
Odour:	Odourless
Odour Threshold:	No data available
pH:	Neutral
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper/lower flammability or explosive limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Relative density:	No data available
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available

9.2 Other safety information

/

10. Stability and reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

Nitrogen oxides (NO_x), Carbon monoxide and carbon dioxide

11. Toxicological information

11.1 Information on toxicological effects

Substance

This product is a mixture.

Mixture

No data available for this mixture.

Acute toxicity

Not classified.

Irritation

Skin: Not classified.

Eye: Not classified.

Corrosivity

No corrosive effect known.

Sensitisation

May cause an allergic skin reaction.

Repeated dose toxicity

Not classified..

Carcinogenicity

Not classified.

Mutagenicity

Not classified.

Toxicity for reproduction

Not classified.

Specific target organ toxicity - single exposure

No data available.

Specific target organ toxicity - repeated exposure

No data available.

12. Ecological information

12.1 Toxicity

No further relevant information 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.

12.5 Results of PBT and vPvB assessment

No further relevant information available.

12.6 Other adverse effects

Water hazard class 3 (German Regulation) (Self-assessment): severe hazard for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13. Disposal considerations

13.1 Waste treatment methods

Dispose of waste according to applicable local, state, and federal regulations.

Contaminated packaging

Dispose of packaging according to applicable local, state, and federal regulations.

Waste codes

Confirm precise waste code with the disposer.

Special precautions

No further relevant information available.

14. Transport information

14.1 UN number

/

14.2 UN proper shipping name

ADR/RID

No dangerous good in sense of this transport regulation.

IMDG-Code / ICAO-TI / IATA-DGR

No dangerous good in sense of this transport regulation.

14.3 Transport hazard class(es)

No dangerous good in sense of this transport regulation.

14.4 Packaging group

Material with low danger.

14.5 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: ☐ yes / ☒ no

Marine Pollutant: ☐ yes / ☒ no

14.6 Special precautions for user

See sections 6 -8.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

15. Regulatory information

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

National Regulations

Water hazard class

Water hazard class 3 (German Regulation) (Self-assessment): severe hazard for water.

Further relevant regulations

/

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

16. Other information

Indication of changes

Entire Revision

Abbreviations and acronyms

PBT: persistent, bioaccumulative, toxic substance (REACH)

vPvB: very persistent, very bioaccumulative substance (REACH)

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