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

Product identifier

Substance name: SDMA vet ELISA Article number: R E F EA203/96

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

Relevant identified uses: Reagent / Immunoassay For in-vitro veterinary diagnostic use only. For professional use only.

Uses advised against: /

Details of the supplier of the safety data sheet:

SDMAvet_7_en

Supplier

DLD Gesellschaft für Diagnostika und medizinische Geräte mbH

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) 40 555 871 0/ Fax +49 (0) 40 555871 11

Emergency Telephone Number

Tel +49 (0) 40 555 871 0

2. <u>Hazards identification</u>

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. <u>Composition/information on ingredients</u>) contain no hazardous reagents in concentrations to be declared.

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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	Highly diluted TMB-solution, acidic, stabilized
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. <u>Firefighting measures</u>

Extinguishing media

Suitable:

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

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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

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8. <u>Exposure controls/personal protection</u>

Occupational exposure limit sulphuric acid: Inhalable fraction: 0,1 mg/m³

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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 cannot 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

Acylation Reagent Powder Antiserum Colored, neutral liquid	Acylation Antiserun Reaction Wash Bur Substrate Stop Solu	rds () ng Reagent () on Reagent () um () um () n Plate () uffer () te () ulution ()	Colored, neutral liquid Polypropylene-Microtiterplate in foil packet Colorless, neutral liquid Slightly bluish, acidic liquid Colorless, acidic liquid, pH < 1
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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.

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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. <u>Regulatory information</u>

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

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.

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Revision date:



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 Gesellschaft für Diagnostika und medizinische Geräte mbH

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) 40 555 871 0 / Fax +40 555 871 11

1.4 Emergency Telephone Number

Tel +49 (0) 40 555 871 0

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Revision date:



2. <u>Hazards identification</u>

2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008 [CLP]: Flam. Liq. 3 H226

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2.2 Label elements

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

Hazard pictograms / Signal word:



Hazard-determining components of labelling Ethanol

Hazard statements:

H226: Flammable liquid and vapour.

H319: Causes serious eye irritation

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)

1

2.3 Other hazards

/

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3. <u>Composition/information on ingredients</u>

3.1 Substances

This product is a mixture.

3.2 Mixture

Substance: DMSO EG-Nr.: 200-664-3 CAS-Nr. : 67-68-5 Content: 60% Classification according to (EG) Nr. 1272/2008: No hazardous product.

Substance: Ethanol EG-Nr.: 200-578-6 CAS-Nr.: 64-17-5 Content: 40% Classification according to (EG) Nr. 1272/2008: GHS02 Danger; Flam. Liq. 2 H225: Highly flammable liquid and vapour

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.

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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.

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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:

1

7.3 Specific end uses

No further relevant information available.

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8. Exposure controls/personal protection

8.1 Control parameters

8.1.1 Components with workplace control parameters Limit Value Type (AGW) Germany

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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 cannot 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.

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9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance - Form: - Colour: Odour: Odour Threshold: pH: Melting point/freezing point: Initial boiling point and boiling range: Flash point: Evaporation rate: Flammability (solid, gas): Upper/lower flammability or explosive limits: Vapour pressure: Vapour density: Relative density: Water solubility: Partition coefficient: n-octanol/water: Auto-ignition temperature: Decomposition temperature: Viscosity: Explosive properties: Oxidizing properties:

Liquid Yellow No data available 38,3 ° Celsius No data available completely miscible No data available 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 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.

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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.

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12.4 Mobility in soil

No further relevant information available.

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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.

Dispose of packaging

Waste codes Confirm precise waste code with the disposer.

Special precautions

No further relevant information available.

14. Transport information

14.1UN number

UN1170; Ethaol; Class 3; PG III.

14.2UN proper shipping name

ADR/RID

UN1170; Ethanol; Class 3; PG III.

IMDG-Code / ICAO-TI / IATA-DGR

UN1170; Ethanol; Class 3; PG III.

14.3 Transport hazard class(es)

May also be shipped as an EXCEPTED QUANTITY in accordance with TDG-IATA/ICAO-IMDG

14.4 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: yes / no Marine Pollutant: yes / no

14.5 Special precautions for user

See sections 6 -8.

14.6 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Possible.

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15. <u>Regulatory information</u>

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.

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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.

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Uses advised against:

1.3 Details of the supplier of the safety data sheet:

Supplier

1

DLD Gesellschaft für Diagnostika und medizinische Geräte mbH

Address

Adlerhorst 15 22459 Hamburg Germany

Information contact

E-Mail: contact@dld-diagnostika.de Internet: www.dld-diagnostika.de

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Tel +49 (0) 40 555 871 0 / Fax +49 (0) 40 555 871 11

1.4 Emergency Telephone Number

Tel +49 (0) 40 555 871 0

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2. <u>Hazards identification</u>

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

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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

Tris(hydroxymethyl)aminomethane

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):

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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: Tris(hydroxymethyl)aminomethane EG-Nr.: 201-064-4 CAS-Nr.: 77-86-1 Content : 20 - 40% Classification according to (EG) Nr. 1272/2008: GHS07 Warning 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 (NOx), Carbon monoxide and carbon dioxide.

5.3 Advice for fire-fighters Protective equipment: Mount respiratory protective device.

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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.

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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.

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8. Exposure controls/personal protection

8.1 Control parameters

8.1.1 Components with workplace control parameters Limit Value Type (AGW) Germany Not required.

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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.

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9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance - Form: - Colour: Odour: Odour Threshold: pH: Melting point/freezing point: Initial boiling point and boiling range: Flash point: Evaporation rate: Flammability (solid, gas): Upper/lower flammability or explosive limits: Vapour pressure: Vapour density: Relative density: Water solubility: Partition coefficient: n-octanol/water: Auto-ignition temperature: Decomposition temperature: Viscosity: Explosive properties: Oxidizing properties:

Liquid Blue Odourless No data available 8.8 - 9.4No data available No data available completely miscible No data available 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

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

10.6 Hazardous decomposition products

Nitrogen oxides (NOx), Carbon monoxide and carbon dioxide

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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.

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12.4 Mobility in soil

No further relevant information available.

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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.

Dispose of packaging

Waste codes Confirm precise waste code with the disposer.

Special precautions

No further relevant information available.

14. Transport information

14.1UN number

14.2UN 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.

14.3Transport 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.

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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.

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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 Gesellschaft für Diagnostika und medizinische Geräte mbH

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) 40 555 871 0 / Fax +49 (0) 40 555 871 11

1.4 Emergency Telephone Number

Tel +49 (0) 40 555 871 0

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2. <u>Hazards identification</u>

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]: Skin sensitisation, Category 1, H317

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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

i i ocaacionary beaconi		
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

1

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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.

Firefighting measures 5.

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 (NOx), Carbon monoxide and carbon dioxide.

5.3 Advice for fire-fighters Protective equipment: Mount respiratory protective device.

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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.

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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

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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.

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8. Exposure controls/personal protection

8.1 Control parameters

8.1.1 Components with workplace control parameters

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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.

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9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance - Form: - Colour: Odour: Odour Threshold: pH: Melting point/freezing point: Initial boiling point and boiling range: Flash point: Evaporation rate: Flammability (solid, gas): Upper/lower flammability or explosive limits: Vapour pressure: Vapour density: Relative density: Water solubility: Partition coefficient: n-octanol/water: Auto-ignition temperature: Decomposition temperature: Viscosity: Explosive properties: Oxidizing properties:

Liquid Yellow-brown Odourless No data available Neutral No data available completely miscible No data available 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 (NOx), Carbon monoxide and carbon dioxide

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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.

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12.4 Mobility in soil

No further relevant information available.

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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.

Dispose of packaging

Waste codes

Confirm precise waste code with the disposer.

Special precautions

No further relevant information available.

14. Transport information

14.1UN number

14.2UN 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.

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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

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Abbreviations and acronyms

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